Privacy and Security Solutions for Interoperable Health Information Exchange

California's Final Assessment of Variations and Analysis of Solutions

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Prepared by:

Authors: **CalOHI & CalRHIO California Team**
Address: 1600 Ninth Street, Room 460
Sacramento, CA 95814

Submitted to:

Linda Dimitropoulos, Project Director
Privacy and Security Solutions for
Interoperable Health Information Exchange

Research Triangle Institute
P. O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

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RTI INTERNATIONAL

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1 Executive Summary

President George W. Bush issued an Executive Order on April 27, 2004, announcing his commitment to promote the use of health information technology (HIT) to reduce medical errors, lower costs, and provide better information to consumers and physicians. The Order called for widespread adoption of electronic health records (EHRs) and for health information to follow patients seamlessly and securely throughout their care. Similarly, Governor Arnold Schwarzenegger issued Executive Order S-12-06 on July 25, 2006, to use HIT to improve patient safety and coordination of care, empower consumers, and guarantee timely access to care specialists. Most importantly, the Governor's Order highlighted his foundational pledge to identify and develop strategies to continue protection of the confidentiality and privacy of patients' health information for the purposes of health information exchange (HIE).

California's participation in the Health Information Security and Privacy Collaboration (HISPC) initiated diverse public and private health care industry involvement toward securing the privacy and confidentiality of personal information in HIE. Recognizing California's unique challenges due to its large population, geography, and industry, multiple stakeholders actively engaged in the three RTI project phases of data collection, solutions analysis, and implementation plan development throughout the eight month contract. The CA Team consisted of a public-private partnership between the California (State) Office of HIPAA Implementation (CalOHI) and the California Regional Health Information Organization (CalRHIO) managed the project. The team also included several nationally recognized legal, health, and technical experts including Manatt, Phelps, and Phillips, LLP, and the consulting firms of Object Health and Medical Management Services, and the RMA Consulting Group.

California is a recognized leader in the protection of personal health privacy. A strong commitment to patient privacy and the protection of health information is demonstrated in the State Constitution and multiple statutes. However, State privacy law, often more stringent than HIPAA, has led to complex State and federal law interplay, often resulting in multiple and conflicting interpretations of applicable law. California stakeholders do not believe that such laws and corresponding business practices and policies are barriers to HIE, but represent California's strong commitment to strong individual privacy protections. Moving forward, California's leaders recognize the foundational legal work that must be completed to create a new legal framework that will increase industry and public confidence in HIE.

Findings

The following summarizes the five major issues identified during the course of the RTI project.

Statewide Privacy and Security Oversight Body – The HISPC project established the first public/private infrastructure to address privacy and security issues. When analyzing potential solutions to address business practice variations, it became apparent that the timeframe for the project did not allow for adequate research, analysis, and testing of privacy and security

solutions options. To adequately address the solution options beyond the project's timeframe for the project, an oversight infrastructure is needed.

Operations – The Health Insurance Portability and Accountability Act (HIPAA) created a distinction in what privacy and security rules apply to which members of the health care industry by applying HIPAA only to covered entities. In addition, stakeholders reported business practices variations stemming from disparate interpretations and understandings of HIPAA, state law, and their intersection. Lastly, stakeholders reported business practice variations that result from entities selecting different approaches to implement those optional and addressable provisions in HIPAA.

Technology – As cited in Operations (above), HIPAA created different security standards for different entities, permitting different approaches to HIPAA implementation. Common security standards designed to protect health information have not been established that apply to all data exchanges as part of an HIE. Common data architecture standards[1] and detailed data classifications[2] have not been developed to differentiate between information needed to support financial transactions and information needed solely for treatment. Further distinction is needed within treatment data and standards for auditing, authentication, access, etc., have still to be reached.

Complexity of Laws – California has many statutes governing the privacy and security of information some of which were designed for different purposes and do not harmonize well. HIPAA preemption complicates the interpretation and understanding of the applicability of State laws pertaining to privacy and security. As a result, entities base business practice policies on a variety of interpretations that direct the access, use, and disclosure of medical information. Widespread variation in interpretations was particularly evident among communities less experienced with collaboration and information exchange. Additional problems arise when health information is exchanged across state lines as the number of applicable statutes and variations in legal interpretations compound.

Trust - California stakeholders concluded that there are certain situations where dynamic tensions may arise between patient privacy and necessary disclosures of medical information. One factor that stakeholders believed inhibits development of HIE privacy and security standards is the 'tension' that results from the conflicting goals between a patient's right to privacy and a provider's responsibilities to disclose health care information for payment and healthcare operations activities. All stakeholders agreed that health information should be exchanged for treatment. However, there appeared to be a belief that the release for payment or health care operations would not be limited to the information or purpose stated for the disclosure, especially given the amount of information available through HIE. This issue should be resolved early on to prevent any further erosion of trust between consumers and providers.

[1] Data Architecture – The method that medical records are organized to ensure that the appropriate data is accessed for the appropriate purpose only by the authorized entity.

[2] Data Classification – The content of the folders that contain medical records, such as a folder that may contain sensitive information that is accessible by limited entities for limited purposes.

2 Background and Purpose

2.1 Purpose and Scope

Project Approach

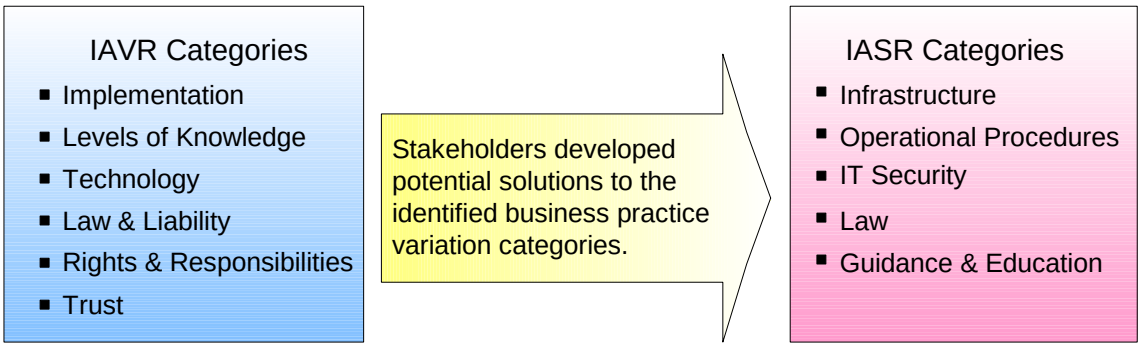
A Steering Committee of 10 private and 10 public health care industry stakeholders has actively overseen the effort and reviewed the project's deliverables. (Member list attached as Appendix A.)

Over the course of several months, information was gathered at seven regional variation meetings held around the state convened involving a wide range of stakeholders including medical groups, hospitals, community clinics, county and state government programs, pharmacies, technology vendors, consumers, privacy advocates, independent physicians, professional associations, and others. Information gathered at the meetings provided perspective on the relevance and interplay of roles, fears, opportunities for improvement, and solutions or best practices already in place.

In the second phase of the project, a Solutions Work Group, made up of selected participants from the regional meetings, prioritized issues and developed potential solutions to address variations in business categories. Potential solutions were organized into five categories that include:

- Infrastructure,
- Operational Procedures,
- IT Security,
- Legal, and
- Guidance and Education.

The graphic below depicts the discussion flow between the IAVR and subsequent reports.



In the final phase of the project, the Implementation Work Group proposed solutions and made the recommendation to establish the Advisory Board. Once established, the Advisory

Board would be charged with creating the necessary committees to address outstanding privacy and security issues affecting HIE. The Steering Committee concurred that the establishment of such an Advisory Board and its subsequent committees would be necessary to create an actionable work plan to resolve outstanding issues and implement privacy and security solutions.

The Implementation Work Group was asked to consider potential solutions rather than a final and comprehensive set of solutions addressing the variations identified in the Interim Assessment of Variations Report (IAVR). During implementation discussions, stakeholders concluded that three components important to informing the decision making process could not be sufficiently addressed:

1) Validation that the information gathered at the regional variation meetings reflects actual business practices,
2) Comprehensive research required to fully develop potential solutions, and
3) The effects of alternative solutions on all HIE participants.

It was not possible to adequately address these components given the project's limited timeframe, methodology, and resources.

Overall, California stakeholders strongly expressed their belief that HIE facilitates high quality and safe care for patients, but that it must also preserve patient privacy and security of their information. Stakeholders view privacy and security protections not as barriers to HIE, but as the foundational to HIE systems and their design.

2.2 Level of HIT Development

California stakeholders are numerous and reflect a wide range of HIE development and maturity. Currently, many California's HIE activities are largely in the planning stage or early implementation. CalRHIO conducts a quarterly inventory of HIT activities in the State and in summer 2006, they identified 16 HIE initiatives at various stages of development. The criterion used to define an HIE initiative is "the ability or intent to share information across at least one boundary." The initiatives in progress may be found in Appendix B. The development stages of state government HIE projects may also be found in Appendix B.

2.3 Report Limitations

RTI's imposed project methodology raised questions of validity and reliability of information collected. Information collected from individuals in a meeting setting and centered on hypothetical scenarios may or may not reflect entities actual day-to-day business practices and may reflect individuals' opinions. Although representative stakeholders from all categories of the health care industry and a wide range of geographic areas participated in the project, the sample size was not large enough to provide statistical validity, nor did RTI require such validation. The inability to conduct surveys or actual HIE system reviews, coupled with time constraints, prevented data collection that accurately and comprehensively represents California business practices.

In addition, the project timeframe did not permit complete analyses of the recommended solutions and their respective consequences. California's solution analysis is more complicated given the volume of privacy law and the interrelationships between legal and regulatory patient privacy protections. Another factor complicating the analyses is California's large medical industry; the Project Team made an effort to reach out beyond RTI's recommended stakeholder groups, but not all groups were equally represented at each workgroup meeting. It is highly recommended that any and all potential solutions to validated variations be tested before they are adopted or an implementation plan is developed.

3 Project Methodology

The following two sections describe independently the methodologies utilized to:

- Identify the business practice and legal variations that may hinder the interoperability of HIE and
- Analyze potential solutions to address the identified variations.

3.1 Variation Methodology

Workgroup Structure: The Project Team leveraged CalOHI's existing workgroup structures for HIPAA implementation, including the State Law Review Project and the existing HIE efforts CalRHIO has identified and coordinated around the State.

The workgroups were consistent with the structure proposed in the RFP:

- The Steering Committee was co-chaired by Cindy Ehnes, Director, California Department of Managed Health Care, and Jo Ellen Hylind Ross, Chief Executive Officer, of Lumetra, a healthcare quality improvement organization. The public/private Committee of 20 members represented health care business executives and leaders from required stakeholder groups. The objective of the Steering Committee's objective was to provide strategic direction and assure stakeholders' objectivity and project credibility. Some members of this committee also attended and participated in the regional Scenario Workgroup meetings as stakeholders.

Exhibit 1 – Report Production Process

- The Legal Committee was comprised of public and private attorneys and other privacy representatives specializing in health care privacy and security law.
- The regional Scenario Workgroups consisted of more than 200 invitees from seven HIE efforts and Regional Health Information Organizations (RHIOs) around the state and represented the required stakeholders in health care business categories. At the meetings these representatives were augmented with participation from county and state government representatives and consumers. Because of California's diverse demographics and geography, the meetings were held in seven communities around the state and more than 125 attendees provided input.

California's Approach

The project in California was launched at a CalRHIO Summit, held on June 22, 2006, in Los Angeles. At the Summit, the nine HIE domains were introduced to interested stakeholders and individuals discussed potential variations in business practices.

Seven regional Scenario Workgroups were convened during the months of August and September 2006. Of the seven regional meetings; Santa Cruz and Ukiah (Mendocino County) are examples of operational HIE efforts, and Sacramento, San Francisco, Irvine (Orange County), Long Beach (Los Angeles County), and San Diego are in different stages of development.

At each session, 15 to 20 stakeholders participated, and up to four project team members facilitated. Stakeholder groups and the total number of participating representatives from each are shown below:

Long Term Facilities and Nursing Homes	6	Consumers/Consumer Organizations.	13
Federal Health Facilities	3	Hospitals	32
Homecare and Hospice	1	Laboratories	2
Clinicians	14	Research Institutions	6
Employers	*	Health Plans/Payers	11
Pharmacies	2	Physician Groups	10
Professional Associations	10	Public Health Agencies	16
Quality Improvement Organizations	1	State Government	25
Community Clinics	19	Correctional Facilities	1
Other – County, Legal Counsel, RHIO and Safety Net			12

* All but ten of the stakeholder participants were also employers, and when the scenario dictated employer input, participants provided an employer perspective.

Guided by facilitators, participants in each Scenario Workgroup meeting reviewed and discussed three to five of the 18 scenarios provided by RTI. Through these open discussions, stakeholders described their business practices and identified issues related to electronically exchanging health information. Potential solutions and implementation strategies to address the variations were also discussed. Some entities responses were based on what they predicted they would do in the situation since they were in the development stages and not yet exchanging information.

The scenarios covered the following issues: treatment, payment, RHIOs, research, law enforcement, pharmaceutical issues, marketing, employee/employer, public health, and health oversight. The following lists the scenarios presented at each of the seven meetings:

Scenario Group Meeting	#	Scenario Title
Sacramento (08/01/06)	2	Patient Care, Substance Abuse Referral
	5	Payment, Payer Access to Electronic Health Records
	18	Health Oversight, Legal Compliance/Government Accountability
San Francisco (08/17/06)	6	Regional Health Information Organization
	14	Employment Operations, Return to Work
	17	Public Health, Homeless Shelters
Santa Cruz (08/29/06)	4	Patient Care, Cancer Screening
	9	Pharmacy Benefit Formulary Alternative
	11	Healthcare Operations/Marketing/New Rehabilitation Center
Irvine (Orange County) (09/05/06)	3	Patient Care, Skilled Nursing Facility
	8	Access by Law Enforcement
	12	Healthcare Operations/Marketing, Newborn
Long Beach (Los Angeles County) (09/06/06)	5	Payment, Payer Access to Electronic Health Records
	7	Research Data Usage, Attention Deficit Hyperactive Disorder
	13	Bioterrorism
	15	Public Health, Tuberculosis
Ukiah (Mendocino County) (09/11/06)	1	Patient Care, Emergency Room
	5	Payment, Payer Access to Electronic Health Records
	6	Regional Health Information Organization
San Diego (09/13/06)	7	Research Data Usage, Attention Deficit Hyperactive Disorder
	10	Pharmacy Benefits, Switching Benefit Pharmacy Managers
	13	Bioterrorism
	16	Public Health, Newborn Screening
	18	Health Oversight, Legal Compliance/Government Accountability

Each meeting opened with an “ice breaker” exercise and participants were asked:

“What one thing would you do to ensure that the right data is in the right place, at the right time, about the right patient, without compromising the patient’s privacy and security of the data?”

Next, stakeholders reviewed three to five scenarios: facilitators selected the scenarios for discussion prior to each meeting and considered the group’s experience and attributes when selecting scenarios. Time was allocated for stakeholders to discuss, from their perspectives, the business practices that applied to the specific scenarios and other issues related to HIE. Aside from issues, stakeholders identified opportunities to further HIE development. A note taker captured the discussion for the team’s analysis and the information served as input for the RTI database, and to inform the Relevant Findings sections of the Interim Assessment of Variations Report.

The Legal Committee validated whether actual State regulation or law drove the business practices reported by stakeholders. Prior to meeting, the Legal Committee was provided with a legal analysis of the scenarios prepared by Manatt, Phelps, and Phillips, LLC, and CalOHI legal staff.

All of the findings, the feedback from the Legal Committee and Scenario Workgroups, and the IAVR were presented to the Steering Committee for its review and approval. Finally, the IAVR was posted to the project team website for review and comment by the Scenario Workgroups, the Legal and Steering Committees, and interested stakeholders. Comments and input directed to the Project Team were reviewed and are reflected, where appropriate, in the Final Assessment and Analysis Report.

3.2 Solutions Methodology

The Project Team identified and invited key stakeholder representatives from the Scenario Workgroups to participate in the initial Solutions Workgroup (SWG). The SWG meeting was held to review the findings from the Scenario Workgroup meetings. An initial Legal Committee meeting was held to discuss the legal issues identified during the Scenario Workgroups. Members of the Legal Committee were invited to participate in the subsequent SWG meetings. A second SWG meeting was held with participants from both the first meeting and the Legal Committee. Interested individuals unable to attend or call-in were invited to share their comments on the project Web site, the project forum, or email comments to a Project Team member. The final two SWG meetings were held via WebEx.

The Solution Workgroups included representation from:

State Government	County Government	Employers
Hospitals/Health Systems	Safety Net Providers	Public Health
Laboratories	Legal Counsel	Physician Groups
Quality Improvement Organizations	Community Clinics & Health Centers	Consumers & Consumer Organizations
Medical & Public Health Schools	Professional Associations & Societies	Regional Health Information Organizations
Pharmacies & Pharmacy Benefit Managers	Clinicians	Payers

Prior to the first meeting, the Project Team notified all stakeholders, including the Steering Committee, that the draft Interim Assessment of Variations Report was posted to the project website for review and downloading. In addition, the Project Team provided participants with supplemental materials, including:

- Key topics and issues identified in the statewide Scenario Workgroup meetings,
- Potential solutions raised in the Legal and Steering Committee meetings, and
- Potential solutions developed by the Project Team.

The Solutions Workgroup participants were asked to review the issues identified in the variations process and prioritize the issues for the purpose of solutions development. The group discussed all identified issues and generally discussed the solutions in the context of:

- Use cases,
- Stakeholders involved,
- The solutions' cost, and
- Possible barriers to adoption.

The group reviewed and prioritized solutions into short-, mid-, and long-term solutions, and tested the solutions' feasibility through general discussions focused on:

- Solutions already in practice,
- Potential alternative solutions,
- Positive outcomes and constraints to those alternative solutions,
- Cost implications,
- Implementation strategies, and
- Best practices.

Throughout the discussions, best practices and potential implementation strategies were documented. Finally, solutions were organized and presented according to the issues they address and summarized into the four RTI-required report categories of:

- Business practice issues,
- State legal and regulatory issues,
- Federal legal and regulatory issues, and
- Interstate issues.

The Project Team then compiled the results from the Solution Workgroup meetings into the draft Interim Analysis of Solutions Report (IASR). The draft Report was posted to the project website, providing an opportunity for any stakeholders involved in the project process thus far to comment. Stakeholders and the Project Team were in agreement that California will need an infrastructure with adequate resources to move forward and achieve any solutions to the privacy and security issues.

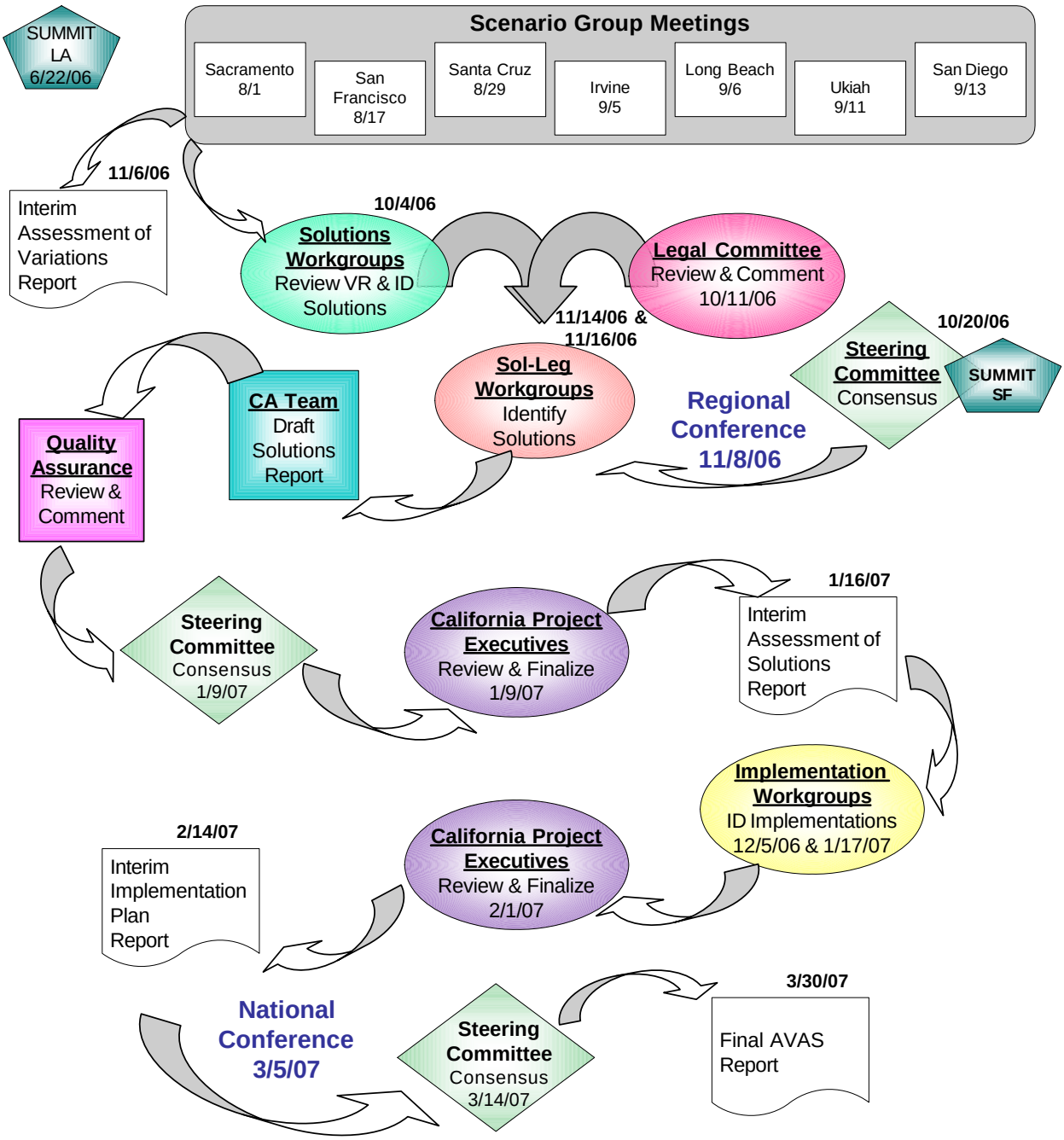
A Steering Committee meeting was held during the development of the IASR to review the Interim Analysis of Variations Report and obtain input on the Interim Analysis of Solutions Report. In addition, in October an expert panel at the CalRHIO Summit discussed several important issues identified throughout the project. The discussion was open to audience participation. Information was gathered from the Steering Committee meeting and the summit and used to augment the report.

As with the process for the Interim Analysis of Variations Report, the quality assurance team reviewed the draft report before it was presented to the Steering Committee for consensus and approval. The Project Team made changes to the report reflecting the Steering

Committee's comments and the report was forwarded to the California Team executives for final approval and submission to RTI.

Additionally, as depicted in the graphic below, the project team convened two implementation workgroup meetings to develop the Interim Implementation Plan Report (IIPR). The report was reviewed by the project executives and finalized. Given the one-month timeframe for development and submission of the IIPR to RTI, it was sent to stakeholders, workgroup members and the Steering Committee for input subsequent to posting on the RTI website. The project team attended the HISPC National Meeting and presented California's findings. Information gathered from other states was shared with the Steering Committee at their final meeting. Based on the IAVR, IASR, and information learned by the project team, Steering Committee, and workgroup members, the Final Assessment and Analysis Report was developed. It was submitted to quality assurance and the project executive members for review and comment before submitting to RTI.

California HISPC Process Flow



4 Summary of Relevant Findings

4.1 Summary of Relevant Findings for Variations

Scenario Workgroups identified over 200 business practice variations that clustered into the following topic areas (listed with the corresponding solution category): **Implementation (Infrastructure), Levels of Knowledge (Operational Procedures – Privacy Policies), Technology (IT Security), Law and Liability (Law), Rights and Responsibilities (Guidance and Education) and Trust**. The levels of knowledge variations centered on the lack of understanding or a variety of interpretations of the HIPAA rules by providers. The rights and responsibilities variations concerned the lack of education and understanding by patients of their rights. Subsequent to the variations process, the team realized that trust was inherent in all of the variation topic areas.

Three of the business practice variations crossed into multiple topic areas. These included:

Covered vs. Non-Covered Entities – The Health Insurance Portability and Accountability Act (HIPAA) created a distinction within the healthcare industry among entities handling individually identifiable health information resulting in HIPAA covered and non-covered entities. Stakeholders reported variations in disclosing health information disclosure practices and differences in the privacy and security protections between covered and non-covered entities. Stakeholders proposed that the privacy and security protections should be applied to health care information, not the entities handling the data.

Legal Complexity- A number of federal and State laws exist governing the privacy of medical information privacy, and these are further complicated by HIPAA preemption. As a result, business practices and policies directing the use and disclosure of medical information are often based on a variety of legal interpretations. Widespread variations in interpretation were most prevalent among communities relatively new to HIE and without a collaborative history. Problems also arose when health information is being exchanged across state lines, as the volume and complexity of laws is compounded.

Data Architecture – There are no data architecture or data classification systems that can adequately identify and separate the health information to ensure that only the "minimum necessary" information for the purpose of the request is disclosed. The data architecture and classification must be based upon privacy laws, policies and business practices.

After the Solution Workgroup meetings and the RTI Regional Conference, and the submission of the interim reports, three issues emerged with implications across all topic areas:

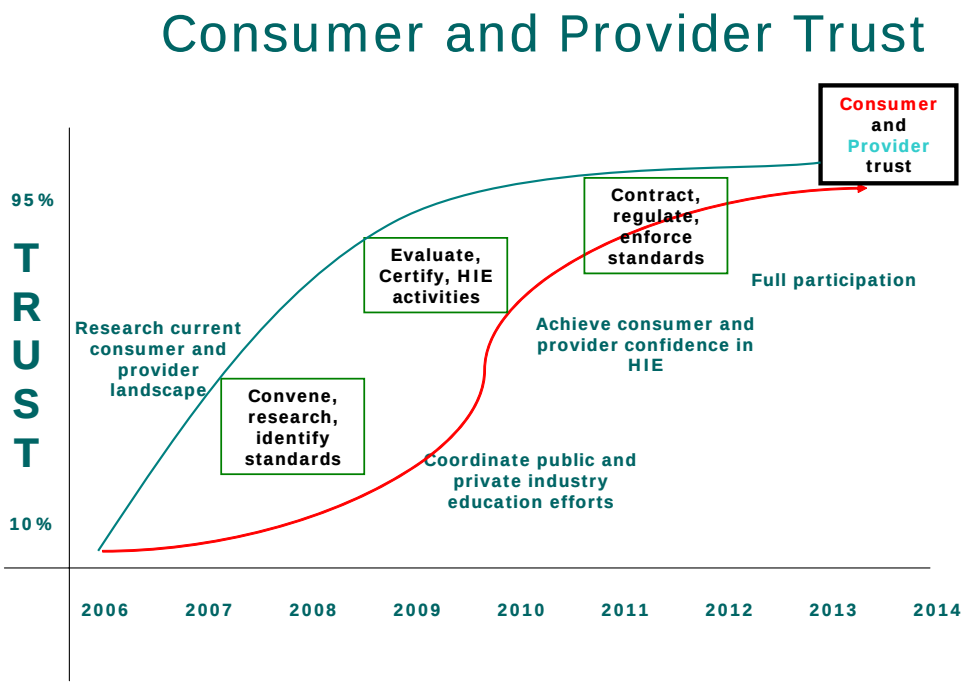
Statewide Privacy and Security Advisory Board - California lacks a governing body to oversee and resolve issues during HIE implementation. When developing solutions to address business practice variations, it became apparent that an infrastructure would be

needed to oversee the research, analysis, testing, and implementation of privacy and security solutions.

Privacy vs. Release of Health Information - California stakeholders concluded that there are certain situations where dynamic tensions may arise between privacy and routine uses of medical information. For example, consumers with behavioral health conditions or genetic conditions may be so concerned about keeping their health records private that they provide inaccurate information or do not seek necessary treatment. Other consumers are fearful that insurers or employers will use their health information to affect them adversely. The widespread use of HIE and the resulting ease of record sharing, raised both consumer and privacy advocate concern. While there was consensus on the need to exchange information for treatment purposes, consumers are concerned about how much information other entities will have access to. Disclosures for payment and health care operations purposes need to be especially scrutinized and assessed separately from disclosures for treatment.

Trust – Underlying all identified variations was the need for trust in different relationships, including:

- Trust among providers to ensure the same level of privacy and security of health information at outside facilities,
- Trust between providers and patients to ensure the safety of the patients information,
- Provider and patient trust that access to HIE systems is limited to only those with a legitimate purpose, and
- Patient trust that their information will not be breached or used inappropriately.



4.2 Legal Aspects of Variations

The scenarios provided by RTI illustrated several issues:

- The amount and complex interaction of State law,
- Differences in coverage, concepts, terminology, and enforcement among State laws,
- HIPAA concepts not found in State law,
- The difficulties in performing preemption analysis,
- State law is constantly changing, thus requiring a new preemption analysis, and
- HIPAA does not apply to all holders of personal health information.

Many of the Scenario Workgroups discussed the lack of consensus in the interpretation of HIPAA, State laws, and preemption analyses decisions. The discussions focused on stakeholders' different levels of knowledge, understanding, and interpretations of the law and preemption decisions. In many cases, stakeholders concluded that the ambiguity of the preemption process and the interaction of State and federal bodies of law lead to the lack of consensus. An analysis providing cites related to the 18 Scenarios is provided in Appendix D.

One healthcare information **privacy** variation in California is the interaction between State law and the Health Insurance Portability and Accountability Act (HIPAA). While HIPAA establishes a floor for privacy protections and patient rights, it allows for considerable state law flexibility. The interaction between HIPAA and state law, results in subjective interpretations and increases differences in policies and actions.

HIPAA preempts contrary state law that is less stringent, leaving differences between states where their laws are not preempted. Less understood is that preemption takes place only when there is a conflict between HIPAA and state law. Where there is no conflict, one may be required to comply with both State law and HIPAA. A patient, health plan, or provider may experience uncertainty in interpreting these laws, leading to different conclusions and actions. Differences increase when entities that hold individually identifiable health information are not covered by HIPAA.

The law governing health information privacy in California consists of State law that survives HIPAA preemption, partially preempted State law, and HIPAA regulations where State law is preempted. Adding to the complexity, privacy provisions in California law may be found in numerous codes depending on the entity or program. In addition, HIPAA contains entire concepts not mirrored in State law. This makes it difficult for individuals to understand their rights, and for providers and government entities to understand and comply with the State laws and HIPAA. Such uncertainty leads to a lack of consensus on application of the laws.

In contrast, no variations were found with respect to State **security** laws.

4.2.1 State Security Law Issues

Like most states today, California has very few laws specifically addressing the security of electronic health information. Because of this, current State security laws pose no immediate barriers to the adoption of interoperable EHR systems in California.

One of the few existing security laws in California is Civil Code § 1798.21, which establishes that State agencies provide appropriate and reasonable administrative, technical, and physical safeguards to ensure the security and confidentiality of records. This section also requires agencies to protect against anticipated threats or hazards to record security or integrity that could result in any injury. Civil Code § 1798.81.5 requires businesses in California to use reasonable and appropriate security measures to protect personal information (defined as name plus Social Security number, driver's license number, financial account number, or medical information). The law exempts HIPAA-covered entities, but not other health care businesses. Another current law, Civil Code § 1798.82, et seq., requires businesses in California to disclose any breach of the security system to any resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

The above cited laws pose no barrier to the adoption of interoperable HIE systems. However, there may be other laws, a lack of law, or future laws that may pose barriers.

4.2.2 HIPAA Security Rule Impact on State Law

The HIPAA Security Rule requires covered entities to adopt physical, administrative, and technical safeguards to ensure the confidentiality, integrity, and availability of electronic protected health information. It appears that the Security Rule's impact would be minimal. The Security Rule is flexible and does not specify particular methods to reach the required security mandates. However, use of different approaches may create issues to HIE.

One issue is that HIPAA does not cover all entities that could participate in an HIE that hold individually identifiable health information. Such entities not covered by the HIPAA Security Rule could be free to construct an HIE system that does not adhere to the same standards as HIPAA. Variations of different security standards could affect important privacy policies and consumer and provider trust, thus reducing confidence in the HIE system.

4.2.3 State Privacy Law Issues (Non-HIPAA)

4.2.3.1 Amount, Variety and Complexity of State Law

California has a strong commitment to patient privacy protections and rights with statutes regulating the privacy of personal health information (PHI). However, these laws are located throughout different areas of California's codes. These laws include:

Title	Statute
Patient access provisions (PAHRA)	Cal. Health and Safety Code §s 123100 et sequence
Basic medical record confidentiality (CMIA)	Confidentiality of Medical Information Act (Cal. Civil Code §§ 56-56.37)
State government	Information Practices Act of 1977 (Cal.

Title	Statute
privacy (IPA)	Civil Code §§ 1798-1798.82)
Public access to records of government (PRA)	Public Records Act (Cal. Government Code §§ 6250-6277)
Insurance Information and Privacy Protection Act (IIPPA)	(Cal. Insurance Code §§ 791-791.27)
Provisions governing records concerning indigents	(Cal. Welfare & Institution Code §§ 17000, 17006, 17006.5)
Confidentiality of Medi-Cal Records	Section 14100.2, (Cal. Welfare & Institution Code § 14100.2) [See also Cal. Code Regs. Tit. 22 § 51009 (2001).]
Administration of Records	Section 10850, (Cal. Welfare & Institution Code § 10850)
Results of HIV/AIDS Tests	Cal. Health & Safety Code §§ 120775, 120975-121020
AIDS	Public Health Records Confidentiality Act,14 Cal. Health & Safety Code §§ 120775, 21025-121035
Lanterman-Petris-Short Act (LPS)	Cal. Welfare & Institution Code §§ 5325-5337
Lanterman Developmental Disabilities Services Act	Cal. Welfare & Institution Code §§ 4514-4518
Information Concerning Alcohol and Drug Treatment	Cal. Health & Safety Code § 11970.5-11977
Birth Defects Monitoring Program	Cal. Health & Safety Code §§ 103830-103850
Cancer Registry Program	Cal. Health & Safety Code §§ 103875-103885
Morbidity and Mortality Studies	Cal. Health & Safety Code §§ 100325-100330 [See also Cal. Code Reg. tit. 17, § 2502 (2001).]

There are also other statutes that govern privacy by specific providers, entities, programs, functions, categories of patients, conditions, or diseases. In addition, California has laws that govern specific medical conditions with extremely sensitive personal information, such as HIV/AIDS, substance abuse, and mental illness. The task of identifying all applicable state law provisions that may affect an activity is onerous. For access to California State laws, see www.leginfo.ca.gov/calaw.

4.2.3.2 State Law Differences

Within State law different Acts apply to different segments, areas, and holders of health information. Some examples of these include:

- The Information Practices Act (IPA) covers State government agencies; the Confidentiality of Medical Information Act (CMIA) covers both public and private health care providers, some health plans, and their contractors; and the Patient Access to Health Records (PAHR) provisions cover health care providers only. Even among just these laws, it is difficult to determine what rules and laws apply to whom.
- The IPA covers "personal information," the CMIA covers "medical information," and PAHRA covers "patient records." Each State law defines critical terms in its own way and differently from the other laws. Again, it is difficult to determine which laws apply to what information.
- The State privacy laws differ in approaches to enforcement, remedies, and penalties. Some mandate criminal penalties, others injunctive relief, and/or civil money penalties. The CMIA allows actions to be brought against violators by the State Attorney General, District, and City Attorneys, etc. All of the State laws differ from HIPAA, including the provision of a private cause of action for a violation.

4.2.4 HIPAA Privacy Rule Impact on State Law

HIPAA applies only to covered entities (health plans; healthcare clearinghouses, or healthcare providers that conduct standard HIPAA electronic transactions). Some potential users of an HIE may be covered by HIPAA but many may not.

4.2.4.1 HIPAA Concepts Not Found in State Law Specific to the Health Care Industry

- The Minimum Necessary Standard: The minimum necessary rule states that HIPAA-covered entities may only make and request disclosures of the minimum information necessary for the purpose of the request.
- Psychotherapy Notes: HIPAA provides that psychotherapy notes have more restricted access than other health information.
- Other concepts include:
  - Verifying identity and authority of persons and entities accessing PHI
  - Extending applicability of the law through a business associates relationship
  - Accounting of disclosures of personal health information

- Allowing requests for alternate confidential communications
- Providing notices of privacy practices
- Allowing requests for restrictions on use and disclosure for treatment, payment, and healthcare operations
- Requiring workforce training
- Requiring workforce sanctions
- Requiring a complaint process
- Mitigating the violations

4.2.4.2 HIPAA Partial Preemption of State Law

Preemption Problems

The HIPAA preemption analysis is one of the most challenging aspects of privacy implementation in California. Entities must either conduct and apply a preemption analysis to:

- **Follow State law** where State law is contrary to but more stringent than HIPAA and no analogous HIPAA provision exists.
- **Follow HIPAA** where HIPAA is contrary to State law but State law is *determined to be less* stringent than HIPAA.
- **Follow both HIPAA and State law** where they are not contrary and it is possible to do both.

The scope of preemption analysis encompasses not only State statutes, but also local ordinances and case law.

- Provision-by-Provision Analysis Required. HIPAA mandates that preemption analysis be by provision. However, it does not define "provision." This is difficult for California because the State law provisions, categories, concepts, terminology, and procedures do not correspond to federal laws and are not structured to facilitate a simple provision-by-provision comparison. For example, the entire CMIA could be considered to be in one provision, since it is found in one section, but it cannot be analyzed as one provision.
- Subject Laws Are Ever-Changing. Preemption analyses are not static; current State laws are frequently amended and new laws will necessitate analyses at least annually. In addition, HIPAA itself is subject to annual amendment through regulation which could cause changes to existing preemption analysis of current State law.
- The Constitutional Bar on Preemption Determination by State Agencies. Under the California Constitution, an agency does not have the power to declare a statute unenforceable, or refuse to enforce a statute on the basis it is preempted by federal law or regulations.

California passed a needed law to allow the HIPAA preemption of California state laws. The Legislature designated that CalOHI with the authority to conduct and adopt HIPAA preemption for determining which provisions of State law are preempted by HIPAA for HIPAA-covered State agencies. This enables those agencies to rely on one set of preemptions to implement HIPAA provisions.

4.2.4.3 Subjective Preemption Problems

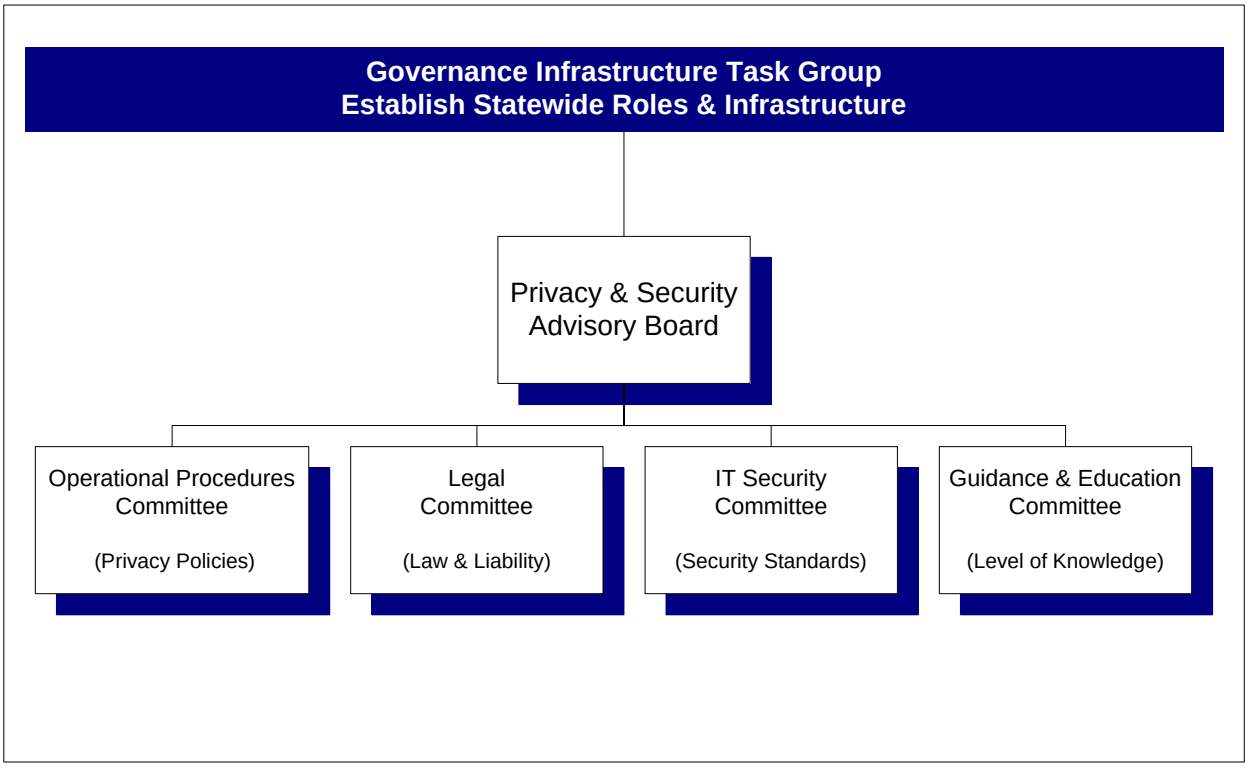
HIPAA preemption analyses require subjective determinations, producing different results for the same State law provision. An opposite yet equally reasonable interpretation may be made based on conclusions that are similar but were reached for different reasons. This results in uncertainty about which provisions are applicable, HIPAA or State law, or a combination of both.

4.2.5 Conclusion

Based on the above legal issues, it is unreasonable to expect patients, providers, and health plans to operate within the myriad of federal and state provisions without consensus interpretations. This may call for some streamlining, standardization, or development of an interpretive body at the state, federal and/or inter-jurisdictional level.

4.3 Summary of Relevant Findings for Solutions

The Interim Implementation Plan Report (IIPR) includes implementation plans that address short-term solutions proposed in the Interim Assessment of Solutions Report. The Interim Assessment of Solutions Report proposed five solutions featuring short-, mid-, and long-term components to acknowledge the magnitude and complexity of HIE issues in California. The first and overarching solution is to create a Privacy and Security Advisory Board (PSAB) to establish the necessary oversight infrastructure to set privacy policies and security standards for HIE. Without the PSAB, it is unlikely that proposed committees' solutions would be developed or implemented. The diagram below illustrates the proposed PSAB and its four committees.



During the solutions analysis portion of the grant, stakeholders informed the Project Team of many implemented solutions to identified variations in business practices, some such solutions were identified as best practices. Due to the size of California, it will be very challenging to document, evaluate the potential to replicate, and educate stakeholders about the solutions for implementation purposes. (See Appendix C for a listing of the identified best practices. Given that these practices were raised in meetings, the Project Team was unable to fully examine each practice to obtain quantifiable data or provide a detailed analysis.)

5 Detailed Assessment of Variations and Analysis of Solutions in Organization Business Practices and Policies

California proposes to establish a high-level Privacy and Security Advisory Board (PSAB) to manage the development, implementation, and/or maintenance of privacy and security standards to be utilized by entities participating in HIE. Four committees will report to the PSAB and each will develop research, review, test, and/or recommend standards and model practices for adoption, implement strategies, and approaches to maintain standards in their defined area. The four committees (and their issue areas) will be composed of IT Security (security issues), Legal (law and liability), Operational Procedures (privacy issues), and Guidance and Education (levels of knowledge and outreach) experts.

5.1 Infrastructure

Detailed Assessment of Variations

The following represent the identified business practice variations that related to the lack of an infrastructure in California.

- Questions about RHIO's and their appropriate functions remain unclear. Should RHIOs' functions include the passive transmission of data or the active examination of data? How is authorization and access to data granted within the RHIO?
- Stakeholders are supportive of patient opt-in or opt-out policies.
- Implementation costs for hardware, software, and support services are a barrier to HIE, especially for small practice providers.
- There is a continuity of care issue if an entity responsible for a patient's care, such as a jail, cannot access the patient's records from the emergency department. EHR will really help facilitate.
- Financial forces in the pharmaceutical industry want access to EHRs and too often data is released without observing the minimum necessary requirement. In many cases, de-identified data would be sufficient for purposes outside of treatment.
- Within small practices, data access is not monitored.

Detailed Analysis of Solutions

Issue Addressed: California lacks a statewide governing infrastructure to oversee the coordination and analyses of HIE issues, the testing and implementation of HIE solutions, and to provide and enforce consistent privacy and security policies among HIE organizations.

Short-Term Solutions

Solution 1:

Establish a statewide public/private HIE Privacy and Security Advisory Board (PSAB) to oversee and facilitate aspects of privacy and security for statewide HIE.

- Identify the proper public and private Board members and chair persons to represent both the health care industry and the State.
- Establish consensus and develop a charter defining the scope of governance, authority, roles, and responsibilities.
- Oversee the various committees which report to the Advisory Board and review the products these committees produce.

Context of Solution	Currently, no governing body exists at the State level to oversee privacy and security policy development, standardization, testing, implementation, and enforcement among California HIE organizations.
Benefits	A committee of public and private stakeholders representing the health care industry in California would be responsible for the development and implementation of statewide policies and standards to which participants would have an opportunity to provide comments and adopt. This effort would limit the development or implementation of duplicate or varying privacy policies and procedures or security standards. The establishment of a statewide advisory board to set standards would promote collaboration and develop trust among participants.
Domains Covered	This solution covers all domains.
Types of HIE Addressed	All public and private sector HIE initiatives.
Stakeholder(s) Impacted	This solution affects all stakeholders.
Stage of Development of Proposed Solution	CalOHI and CalRHIO have formed a public-private partnership Steering Committee that oversees the work of the current RTI contract. This Committee may form or be involved in the formation of the Advisory Board members.
Extent Solution in Use	Not in use.
Range of Stakeholders	All
Barriers to Proposed Solutions	• Lack of funding • Lack of support and participation among stakeholders

- Lack of staffing
- Lack of a common vision and purpose
- Different levels of development among public and private entities

Mid-Term Solutions

Initial issues to be addressed by the board include:

Solution 1A

- Oversee and approve the establishment of committees.
- Prioritize issues and assign to appropriate committees.
- Monitor the development of solutions and implementation plans for the assigned committees.
- Oversee solution testing.
- Review, comment, and approve the recommended committee solutions and implementation plans.
- Submit recommended solutions and implementation plans to PSAB sponsors.
- Advocate best practice technology solutions that ensure the privacy and security of health information.
- Maintain involvement and align efforts with federal initiatives.

Solution 1B

Oversee the development of statewide certification standards or contractual standards that intermediaries can use to establish trust among entities participating in HIE.

Solution 1C

Establish enforcement mechanisms to address privacy or security violations occur among HIE participants.

Long-Term Solutions

Solution 1D

- Oversee and promote the common use of standard business practice "paperwork" by providing electronic, generic templates and tools, such as:
  - Business Associate Agreements (BAAs) with standard privacy and security language,
  - Health record content
  - Standard contract language between vendors and providers,
  - Notices of Privacy Practices (NPPs) in a standard, easy to read format, and
  - Authorization and consent documents in a standard, easy to read, and HIPAA-State law compliant format.

5.2 Operational Procedures (Privacy Issues)

Detailed Assessment of Variations

The following represent the identified business practice variations related to operational procedures and affecting the privacy of health information:

- The complex legal structure and the interaction of State and federal law create disparate levels of knowledge, understandings, and interpretations of basic privacy requirements among stakeholders, sometimes resulting in the restrictive sharing of health information. Provider and health plan staff fear HIPAA penalties and subsequently interpret HIPAA restrictively, potentially preventing or interrupting HIE.
- Stakeholders understand that health information may be shared for treatment, but stakeholders must often make judgment calls when determining the amount of health information to share for payment and health care operations purposes. Interpreting HIPAA's "minimum necessary" requires additional time and resources and thus increases the risk of delayed payment, as a result, some providers may not adhere strictly to minimum necessary.
- It is not clear for providers when and how to apply "minimum necessary" when a state oversight agency requests health information.
- The line between permitted and prohibited disclosures outside of treatment is unclear.
- Stakeholders understand that sensitive health information (i.e. substance abuse, HIV, mental health information, etc.) requires extra protection. However, there is not consensus about what protections are legally required.
- Providers typically submit more information than is necessary to ensure payment, especially since "minimum necessary" is not well defined or clear.
- Medical industry entry-level staffs do not have the necessary training, skills or knowledge to interpret and apply the various complex health information laws.
- It is difficult to manage all layers of various laws that apply to different types of information and require different levels of sensitivity or protection. Fear of misinterpretation drives staffs' tendencies to apply the strictest controls.
- The great number of federal and State laws, coupled with preemption analysis, leads to increasing opportunities for misunderstanding and misinterpretation among staff and personnel.
- The boundary between when "minimum necessary" is and is not applied is unclear.
- Patient health information is needed immediately in an emergency department.

- Transportation personnel need appropriate patient health information to ensure their personal safety and the safety of the patient and themselves. (e.g., transporting from jail to the emergency department.)
- Confusion exists between how and when to use the HIPAA Notice of Privacy Practices (NPP) or the patient authorization, for example, a hospital reported that it notifies patients about its marketing practices in its NPP and asks patients to cross out those disclosures they do not wish to make.
- Stakeholders lack of knowledge about appropriate disclosures for marketing and fundraising purposes.
- Confusion exists about what information to report to public health entities, potentially leading to misreporting.
- There are no federal protections for data once released by a HIPAA covered entity. For example, a public health authority may inadvertently serve as an inappropriate source for disclosing health information.
- The lack of standardized forms, data classification, and protocols among treatment facilities is a barrier to HIE.
- The question around ownership of individual patient records remains unresolved and creates difficulties for patient access and health record verification.
- Organizations with electronic medical records may still choose to use paper and some payers are not willing to engage in electronic transfer.
- Treatment facilities currently have disparate practices when handling health information internally and externally.
- There is a conflict between the Joint Commission's requirement that hospitals keep records for all of their patients and the counties' desire for centralized patient records.
- Providers are subject to pressures from both the payers and patients, creating a tension between payment and patient interests.
- Not informing patients regarding their consent or authorization is a barrier to HIE.
- IT staff members do not sufficiently understand business needs enough to appropriately limit data disclosures. The business/program and IT staffs need to discuss and agree on what data is needed for specific purposes. A disconnect also exists between the business/program and legal staffs.
- If a drug prescription is non-formulary, the patient is expected to follow up with his or her physician and request the formulary drug instead. If the non-formulary drug is purchased, the patient must pay the difference in price.
- In county systems, there is not an alert about patient drug coverage, as a result, physicians must manually determine whether the prescribed drugs are formulary or non-formulary. The increase in mail order pharmaceuticals may enhance the problem.

- Some providers misunderstand that a Business Associate Agreement (BAA) is not necessary to exchange information with pharmacies.

Detailed Analysis of Solutions

Issue Addressed: Health care industry professionals exhibit inconsistent understandings of the rules governing the privacy and security of health information. This may result in a lack of trust among stakeholders and interfere with HIE.

Short-Term Solutions

Develop and recommend a structure, purpose, membership, and activities for a committee of medical industry stakeholders from the public and private sectors. This committee will identify variations in business practices related to privacy and analyze all solution alternatives to arrive at a recommended solution. The committee will oversee the testing of the solution and make any necessary revisions based on the testing results. The committee will make recommendations to the Privacy and Security Advisory Board (PSAB). In conjunction with the Guidance and Education Committee, it will propose approaches to ensure consistent understanding, implementation and maintenance of standard business procedures and policies within the health care industry to ensure individuals' rights and responsibilities concerning health information privacy and security.

Context of Solution	Entities participating or planning to participate in HIE have different privacy and security policies, inhibiting the interoperability and health information sharing.
Benefits	This solution addresses the development or implementation of varying policies and procedures to protect the privacy of health information. The use of a statewide work group to set standards would promote collaboration and develop trust among participants.
Domains Covered	Domains 2, 7, and 9.
Types of HIE Addressed	This would assist in all types of HIE among stakeholders.
Stakeholder(s) Impacted	All stakeholders.
HIE Barriers Addressed	Addresses the current inconsistent organizational privacy policies.
Stage of Development of Proposed Solution	Members of the Scenario Work Groups, Solution Work Groups, Implementation Work Groups, and the Steering Committee may transition to become members of this committee.

Extent Solution in Use	None known at this time.
Range of Stakeholders	All.
Barriers to Proposed Solutions	• Lack of funding and staffing • Lack of support and participation among stakeholders • Lack of a common HIE vision and purpose • Different levels of development among public and private HIE entities

Mid-Term Solutions

Solution 4A

Examine the federal and State provisions governing ownership of and responsibilities to maintain and control patient data and records.

Solution 4B

In conjunction with the Legal Committee and employing use cases for analysis, recommend, if necessary, a consistent interpretation or application of ownership, stewardship and/or custodianship in regard to patient data and records.

Long-Term Solutions

Solution 4C

Examine use cases to analyze and develop solutions for issues concerning:

- Patient option to participate in HIE,
- Patient consent to release information for electronic transmission, i.e., use and disclosure of patient information for treatment, payment, and/or health care operations, [consent for use and disclosure would require examinations of the ramifications of patient choice and standardizing consent forms.]
- Patient informed notification concerning HIE participation, and
- Integrity of information received from an outside entity's system and subsequent provider liability.

5.3 IT Security Standards

Detailed Assessment of Variations

- Overall, relatively small practice physicians have comparably less resources and exhibit a technical lag and disconnect in comparison to large practices, although there are a few notable exceptions.
- A willingness to use technology will bring some entities to digitize health information before other entities. Those entities need to be able to bridge to communities or entities that are not at the same level of electronic health information, until their technology meets the standard platform.
- Stakeholders are unable to authenticate users or verify e-signatures from outside organizations.
- Audit logs may not be common practice and, when used, may not be reviewed frequently enough to reliably determine inappropriate access, nor are sanctions consistently applied for such inappropriate access.
- IT staff need to be, but are not currently, audited to protect against internal breaches.
- Firewalls do not always exist at both ends of a health data transmission.
- Data is not always encrypted or encrypted at an adequate level when transmitted between stakeholders.
- There are no mechanisms in place to authenticate a physician's identity.
- There are no established or standard security protocols governing HIE among organizations (e.g., encryption, integrity, etc.).
- There is no role-based access distinguishing among access to treatment data, sensitive data and data that are more general.
- There is no role-based access for health information related to payment.
- Systems are not capable of classifying data into purpose-specific sets to ensure appropriate access for treatment, payment, operations or other purposes.
- A detailed data classification system does not always exist to address the appropriate release or withholding of data: determining such appropriate releases requires the application of minimum necessary.
- Stakeholders were not aware of a classification system to facilitate data sorting and prevent inappropriate disclosures of health information to public health agencies.
- Embedded errors in current records deter the automated entry of current records into EHRs.
- Data transmission is not always secure.

- Data elements are not standardized.
- Users' needs for read-only access to a data repository and write access for treatment purposes must be defined.
- Taxonomy-level clarification does not exist to determine role-based access.
- Stakeholders are concerned about researcher's access to data and subsequent use of released data.
- Stakeholders are concerned that the technology may facilitate quick data mining of health information for monetary or marketing purposes.
- Some systems do not track all disclosures of health information.
- Some systems do not track patients who may seek services from multiple providers, i.e., drug seeking behavior.
- Resources and skilled staff are not always available to determine if de-identified data would satisfy a public health request.
- Standard algorithms and data sets do not exist to assist in clinical decision-making and their development will be very costly.
- Current systems do not consistently track the disclosure of patient health information, as required for HIPAA compliance.
- There is not a standard patient identifier, for example, babies' names are often changed between delivery and their first physician visit.

Detailed Analysis of Solutions

Issues Addressed: Despite the many security standards, there is no consensus on which standards best protect health information for electronic exchange.

Short-Term Solutions

Solution 2:

Establish the IT security committee to:

- Analyze, select, and recommend implementation strategies to the HIE Privacy and Security Advisory Board (PSAB) to establish standard security policies, procedures, and technology controls, and
- Provide leadership to
  - Establish a standard business practice model,
  - Convene a statewide summit to share technology methodologies that address HIE privacy and security, and
  - Promote and ensure collaboration with other states and the federal government in the national HIT efforts and related activities.

Context of Solution	Entities participating in or planning to participate in HIE have implemented a wide range of security controls, hindering the interoperability of HIE. If the protections rendered through those security controls are ineffectual, the data contributors do not want to be held accountable for inadequate protections or procedures where the data is sent. Therefore, without common standards entities will not exchange data.
Benefits	Adoption of common security standards among HIE participants prevents the development or implementation of duplicate or varying technology policies and procedures. The use of a statewide committee to set standards promotes collaboration and develops trust among participants.
Domains Covered	Domains 1-6.
Types of HIE Addressed	All types.
Stakeholder(s) Impacted	All.
HIE Barriers Addressed	IT security barriers.
Stage of Development of Proposed Solution	CalRHIO has developed and issued an HIE technology standards roadmap for California; however, additional work should be done focusing on the roadmap's security aspects.
Extent Solution in Use	Unknown.
Range of Stakeholders	All.
Barriers to Proposed Solutions	• No focused attention on standards review and consensus • Lack of support among stakeholders, including payers/plans, vendors and providers • Lack of participation among stakeholders • Lack of staffing • Different levels of development among public entities • Lack of a common vision of HIE • Unknown costs to stakeholders for migrating to and implementing standards and high costs of security controls.

Mid-Term Solutions

Solution 2A

Analyze and identify standards to address specific initiatives, i.e., e-prescribing, public health registries, emergency room treatment needs, personal health records, etc.

Long-Term Solutions

Solution 2B

To the extent not addressed through analysis and resolution of issues related to initiatives, analysis, and identification of standards to address:

- Data transfer among entities through a tested model,
- Communication of patient identity,
- Standard digital signature protocols,
- User authentication criteria,
- Audit criteria and mechanisms,
- Certification for HIE intermediaries by a governing body, and
- Limiting data to:
  - the minimum necessary for the requested purpose, or
  - that which has been authorized by the patient, or
  - existing data sharing agreements.

5.4 Legal Issues

Detailed Assessment of Variations

- Stakeholders asserted that there is no common definition of a patient medical record.
- Differences in state law and stakeholders' understandings of preemption may result in business practice variations, that may hinder interstate HIE. It is unclear whether the requesting or receiving state's laws governs the information request.
- Under CA law, HIV requires separate authorization, but it's hard to edit such sensitive data out of the patients' medical records or sequester it appropriately.
- The HIPAA Transactions and Code Sets rule for claims is not clear regarding what information is minimally necessary to receive payment.
- Stakeholders have various perceptions about the degree to which privacy laws are enforced. Some individuals perceive aggressive enforcement as a threat and subsequently withhold data and interrupt HIE, whereas others believe that a lack of real world enforcement undermines the credibility of HIE.
- Stakeholders believe that information is released or used inappropriately for the purposes of healthcare operations, marketing and research, as there is no clear distinction among these activities. For example, individual internal "studies" based on quality of care are considered healthcare operations.
- HIPAA's complexity, the Common Rule (IRB's), and other pertinent laws, confuse the legal analysis and application to individual research studies.
- HIPAA permitted disclosures for law enforcement purposes are interpreted differently and may incur legal costs.
- Laws in other states may not be as comprehensive as California law. It is unclear whether liability rests with the entity giving the information.
- Stakeholders asserted that the privacy and security of health information may not be the most important factor in response to a bio-terrorist event.
- Health information privacy may be at risk because there is no common standard for users accessing data, such as non-covered entities under HIPAA.
- Public Health is a hybrid entity under HIPAA but some Public Health components, such as food and water sanitation, are not HIPAA covered entities.
- Some entities not covered by HIPAA, may be sharing data in a non-standard method.
- Providers have difficulty determining parental rights to children's' health information in the case of divorced parents.

- California stakeholders are reluctant to disclose data to states with comparably weaker privacy protections.

- Privacy rules governing some public health issues may not exist or be clear. For example, there is law on tuberculosis but not on avian flu. Providers have been using the tuberculosis law as a guideline to address avian flu cases, but its implementation is confusing.

- Privacy may be at risk if the Department of Housing and Urban Development does not adhere to the same standard as the entities required to input health care data into their system.

- It has not been determined how all the various privacy laws interface. It is not feasible for one person or entity to fully understand the legal complexity resulting from the convergence of all laws that affect the privacy and security of health information. Laws are disjointed and interface at the federal and state levels, among states, among sections of state law, among state oversight agencies, among state agencies and local agencies, and between public and private providers. While laws are often added, changed or deleted, they are not integrated based on a functional redesign.

- Business Associate Agreements (BAAs), which are intended to facilitate implementation of applicable law, are sometimes not reliably implemented. It is not clear when different agreements should be used, (i.e. BAAs, trading partner agreements, data access agreements, health information exchange agreements, etc.) As business procedures and relationships are defined, the legal contractual framework will need to support the parallel implementation of health related law.

- Interoperability will involve covered entities and non-covered entities subject to different legal restrictions and constraints. Stakeholders felt that privacy and security protections should be applied to the data, rather than to entities as is the current practice.

- The complex legal structure and the interaction of State and federal law create differences in stakeholders' level of knowledge, understanding, and interpretation of basic privacy requirements, sometimes resulting in the restrictive sharing of health information. At the staff level, employees fear HIPAA penalties and subsequently interpret HIPAA restrictively, sometimes preventing or interrupting HIE.

Detailed Analysis of Solutions

Issue Addressed: Within the health care industry, there are multiple interpretations and applications of federal and State provisions governing the privacy and security of health information, resulting in different approaches to health information privacy and security in California.

Short Term Solution

Solution 3

Develop and recommend a structure, purpose, membership, and activities for a committee of public and private health care industry stakeholders and their legal counsel. The legal

committee would identify and recommend solutions to the HIE Privacy and Security Advisory Board (PSAB) concerning legal issues among federal provisions, State provisions, and State law preemption. The legal committee would also provide legal analysis on alternative solutions to privacy and security issues for the other committees.

Context of Solution	Stakeholders employ a variety of means to protect health information, depending on the information holder's knowledge, interpretation of laws, or circumstances in which the information resides.
Benefits	Consensus among the health care industry on a common set of privacy and security laws that protect health information will prevent the development or implementation of duplicate or varying legal interpretations. The use of a statewide committee to establish common interpretations around the application of federal and State provisions would promote collaboration and trust among stakeholders.
Domains Covered	Domains 8 and 9.
Types of HIE Addressed	Will address all aspects of HIE in the public and private sectors.
Stakeholder(s) Impacted	All.
HIE Barriers Addressed	Unknown.
Stage of Development of Proposed Solution	This new solution will leverage existing organized efforts in this field including the California Team's Steering Committee and Workgroups. CalOHI's foundational legal work would supply the Legal Committee with the necessary information to begin analyzing policies and making recommendations.
Extent Solution in Use	Not in use.
Range of Stakeholders	All.
Barriers to Proposed Solutions	• Lack of funding, staffing, support and participation among stakeholders • Lack of a common HIE vision and purpose • Inability to agree on core principles, goals or laws • Different levels of development among HIE entities

Mid-Term Solutions

Solution 3A

Compile an index of federal and State privacy and security provisions that affect HIE.

Solution 3B

Analyze the impact of privacy and security requirements on HIE entities and explore the potential impacts of:

- Applying standards to all HIE participants, or
- Applying privacy and security requirements to all individually identifiable health information, regardless of its location.

Solution 3C

Create an authoritative and public reference that compiles, compares, and identifies the differences in the federal, HIPAA, and State provisions governing the privacy and security of health information.

Long-Term Solutions

Solution 3D

Evaluate the feasibility and applicability of a model state law or model state contract for the privacy and security of health information and, if appropriate, work with other states and national efforts to develop and recommend such models.

Solution 3E

Develop an implementation plan for improving and standardizing statutes affecting HIE.

Solution 3F

Develop a plan to resolve the ambiguities among California law, HIPAA, and HIPAA's preemption of State law.

5.5 Guidance and Education

Detailed Assessment of Variations

➢ Consumers and providers will not be aware of HIE privacy and security standards that are adopted unless an education effort is undertaken. There is a gap in knowledge that includes:

- Ownership of individual patient records,
- Consumers ability to affect their physicians' decisions regarding what health information is shared,
- Physicians ability to access their patients' *complete* health records and to avoid liability issues,
- Stakeholders have various perceptions of HIPAA sanctions, ranging from paranoia of the "HIPAA police" to the belief that violators are not being held accountable, and
- Accountability and understanding the responsibility to protect the privacy of patients' health information around Interactive Voice Response (IVR) systems is not clear and may affect data integrity and patient privacy.

➢ There is a lack of trust among health care providers and between patients and their providers, potentially interrupting HIE.

➢ Stakeholders are uncomfortable with patients' lack of knowledge and education about their individual rights and personal health information.

➢ Patients may trust physicians accessing their medical records, but are not likely to trust third parties (i.e. employers, marketers, insurance companies) accessing their health information.

➢ Patients are concerned about payers and employers gaining access to their health information.

➢ Patient health data is valuable.

➢ Increased data sharing lead to greater risk of breaches and a greater chance of public concern.

➢ The current lack of transparency may cause the public to question where health information is going, and they may distrust or oppose EHRs.

➢ Patients need to be educated about the benefits of HIE.

➢ Confusion exists around stakeholder roles and procedures, making the protection of health information difficult. Stakeholders were not aware of established role interfaces among providers, state agencies, the University of California system and other states.

Detailed Analysis of Solutions

Issues Addressed: The project team identified disparate levels of knowledge among stakeholders and health care industry staff about the privacy and security requirements affecting HIE. Consumers also exhibit varying levels of knowledge about their health information rights and responsibilities and the benefits and detriments of HIE. The cumulative differences in knowledge among patients and health care industry staff lead to mistrust thus hindering participation in HIE and affecting patients' abilities to participate in the maintenance of their health records.

Short-Term Solutions

Develop and recommend a structure, purpose, membership, and activities for a committee of health care industry stakeholders from the public and private sectors. The committee shall identify opportunities to educate health care industry stakeholders and patients on privacy and security provisions and the benefits and detriments of HIE for recommendation to the HIE Privacy and Security Advisory Board (PSAB).

Context of Solution	There are different levels of knowledge about privacy requirements exist within the health care industry that may impede the exchange of information and inhibit trust. Patients' lack of knowledge about their rights leads to trust issues, and industry stakeholders and privacy advocates agree that patient trust will be critical to the success of HIE.
Benefits	The outcomes from the guidance and education committee would assist all HIEs to improve health care industry staff and patient knowledge about health information privacy and security protections and the benefits of HIE. Stakeholders strongly believe that education will lead to greater trust among all parties affected by HIE.
Domains Covered	All.
Types of HIE Addressed	All.
Stakeholder(s) Impacted	All.
HIE Barriers Addressed	Disparate Knowledge and awareness of HIPAA and CA State privacy regulations creates confusion and mistrust among patients who must ultimately support HIE among providers.
Stage of Development of Proposed Solution	CalOHI oversees State departments' HIPAA implementation and provides guidance on HIPAA regulations. Its work, along with that of the CMA, CHA, and CalRHIO could assist in the development of materials and programs for educational purposes. CalRHIO has successfully convened and hosted five statewide summits focused

	on HIE issues, including a summit focused on privacy and security in October 2006.
Extent Solution in Use	Unknown.
Range of Stakeholders	All.
Barriers to Proposed Solutions	• Lack of funding • Lack of support and participation among stakeholders • Lack of participation among stakeholders • Lack of staffing • Lack of a common vision and purpose • Different levels of development among public and private entities

Mid-Term Solutions

Solution 5A

Establish the committee to:

- Develop and recommend education curriculum and an implementation process to improve the medical industry's knowledge of privacy and security requirements, and
- Develop and recommend curriculum to educate patients about their rights and responsibilities to enable them to protect and monitor their health care information.

Long-Term Solutions

Solution 5B

Recommend methods to implement:

- Public awareness and education campaign,
- Health information privacy and security speakers' bureau,
- Website and blog, and
- Education and resource portal.

6 National-Level Recommendation

The stakeholders recommended that a national effort provide structured, coordinate, and transparent guidance to the current national standard setting bodies. The national effort should provide an opportunity for stakeholders, through state processes, to comment on proposed standards. Such efforts could lead to the adoption of recognized model laws, contracts, policies, and procedures among HIE entities.

The stakeholders recommend that all federal programs and departments conduct standardization efforts that complement and parallel to individual states' efforts. The coordination of privacy and security standards for health information for the federal programs will facilitate nationwide implementation of HIE.

The stakeholders recommend that the federal Department of Health and Human Services (HHS), or an agent such as American Health Information Community (AHIC), be a coordinating body and establish a national committee to recommend HIE privacy and security educational activities. Consistent national educational messages to consumers and health care industry members may lead to greater public understanding and HIE participation, as well as fewer barriers to interstate exchange.

Finally, the stakeholders recommend that the federal government coordinate with states to resolve the variance in application of federal privacy and security provisions.

California recommends that a national emphasis be placed on the development of privacy and security standards to prevent the need to retrofit complex technologies at great costs and to avoid public clamor for hasty remedies after serious compromises occur.

7 APPENDIX A

Stakeholder Membership List

LAST	FIRST	ORGANIZATION
Aagaard	Jana	Law Office of Jana Harder Aagaard
Ackerman	Linda	Privacy Activism
Anderson	Patrick	Los Angeles Department of Health Services
Anderson, MD	Peter	Community Board Member
Andrews, Dr.	Keith	Sacramento County Department of Health and Human Services
Anolik	Sharon	Blue Shield of California
Armentrout	Nancy	California Association of Health Facilities
Babakanian	Ed	UCSD
Bach	Michele	Sacramento County
Balingit	Albert	California Department of Consumer Affairs
Barrera	Jody	Orange County Health Care Agency
Beal	Steven	Talbert Medical Group
Beecham	Nancy	Retro Medical Billing Inc.
Beighe	Bill	Physicians Medical Group
Bhayani	Manisha	Coalition of Orange County Community Clinics
Birnbaum	Cassi	Children's Hospital
Book, MD	Eric	Blue Shield of California
Bost	Sue	California State Department of Finance
Boyce-Smith	Gifford	Blue Shield of California
Boyle	Patrick	Quest
Burlew	Sylvia	Mendocino Coast District Hospital
Buurkarl	Marti	Hill Physicians Medical Group
Campbell	John	County of Los Angeles Department of Mental Health
Campbell, RHIA	Thea	Cedars-Sinai Medical Center, Health Information Department
Carlisle	Vicki	Dominican Santa Cruz Hospital
Castillo	Dan	Orange County Health Care Agency
Cathey	Walter	Institute for Community Pharmacy
Chandler	Marcella	Ukiah Mental Health Center
Chapin	Sandra	Consumer Federation of California
Chernis	Bob	Central Coast Alliance for Health
Chessen	Donna	Board of Directors
Clark	Janet	St. Mary Medical, Director of Health Information
Colfax	David	Board of Supervisors Office
Coren	Andy	Mendocino Medical Group
Cosker	Kennedy	Santa Cruz County Health Services Agency

LAST	FIRST	ORGANIZATION
Cresap	Elena	Sharp Mission Park
Deckert	Churck	Sharp HealthCare
Deford	Drex	Scripps Health
Dharkar-Surber	Sapna	Hospital Association of SD&IC
Dickey	Kevin	Contra Costa County
Dinsmore	Kathleen	Los Angeles Department of Health and Human Services
Dittemore	Leo	Healthcare Partners
Duong	Toan	Coalition of Orange County Community Clinics
Dyer	Irene	Los Angeles Department of Health Services
Ehnes	Cindy	California Department of Managed Health Care
Elmer	Tracy	Health Information Mgmt, Sharp Rees-Stealy Medical Centers
Escoboza	Steve	President/CEO, Hospital Association of SD&IC
Espinoza	Richard	4th District County of Los Angeles, Health Deputy
Ettin	Frank	Blue Cross of California
Evans	Dennis	Molina Health Care
Evans, MD	Douglas	Sutter Health /CPMC
Faer	Maria	Kaiser Permanente, National Privacy and Security Office
Farry	Bill	CalOptima
Faulk	Robert	Medical Society of Mendocino/Lake Counties & Foundation for Medical Care
Ferrel	Stephanie	City of Los Angeles
Ferris, MD, MS	Todd	Stanford University
Ficco	Kathy	Community Health Clinics and Programs, St. Joe's
Fisher	Debra	Sharp HealthCare
Fleisher	Steve	Blue Shield of California
Flick	Jeff	Centers for Medicare and Medicaid Services
Frank	Lynn	Sacramento County Department of Health and Human Services
Friery	Tena	Privacy Rights Clearinghouse
Fumanski	Denise	Kennon S Shea & Assoc
Gannon	Gail	Consultant, JHD Group
Gates	Robert	Orange County Health Care
Gatewood, MSW	Hunter	California Health Care Safety Net Institute
Geyer	Ann	Tunitas Group
Givens	Beth	Privacy Rights Clearinghouse
Guerrero	Sylvia	Los Angeles County Department of Mental Health
Guterman	Jeff	Los Angeles Department of Health Services
Gwin	Donna	City of Los Angeles, Senior Deputy City Attorney
Haas	Eric	UC Davis Center for Health & Technology
Halich	Luba	Palomar Pomrado Health

LAST	FIRST	ORGANIZATION
Hamilton	Ann	Mendocino Informatics, Inc.
Hanson	Catherine	California Medical Association
Hanson	John	MedEPass
Harms	Dorel	CA Hospital Association
Harry, M.D.	David	UC Davis Medical Center
Hazel	Karen	Kaiser Foundation Health Plan
Hearing	Tim	Sutter Health
Heller, M.D.	Barry	St. Mary Medical
Hess	Bill	Committee on the Shelterless
Hinkley	Gerald	Davis Wright Tremaine, LLP
Hogarth, MD	Mike	UC Davis
Holmquest	Don	CalRHIO
Holt	Christopher	California Department of Managed Health Care
Homan	Dzana	Future Kids
Huber	Cheri	Napa County
Hunt	Jim	Countywide Services Agency
Isaacs, M.D.	Richard	Kaiser Permanente South Sacramento Medical Center
Jaffe, MD, MBA	Rory	University of California President's Office
Jimenez, MD	Ron	Santa Clara Valley Health and Hospital Systems
Johnson	Katherine	PHFE Management Solutions
Kasch	Ed	Healthcare Partners
Kaufman	Ken	St. Joseph's Hospital
Keith	John	MemorialCare Health Systems
Keville	Terry	Manatt, Phelps & Phillips, LLP
Khalsa	Rama	Santa Cruz County Health Services Agency
Kikuchi	Richard	CalOptima
Kim	Katherine	Kim Consulting
King	Jeff	Potter Valley Community Health Care
Knapp	John	The Coastal Mountain Group, Inc.
Kolb	Michael	Alvarado Hospital Medical Center/SDRI
Kopp	Walter	Menlo Medical Clinic
Korican	Melissa	Sharp Rees-Stealy Medical Centers
Labrie	Marvin	Physicians Medical Group
LaMoreaux, RHIA	LaVonne	California Health Information Association
Landry	Laura	City of Long Beach Department of Health and Human Services
Leader	Eric	Catholic Healthcare
Liederman	Eric	Kaiser Permanente
Littman, RN MSN	Eleanor	Health Improvement Partnership

LAST	FIRST	ORGANIZATION
Lohnes	Maggie	Huntington Hospital
Loubet	Henry	Keenan & Associates
Lourie	Serena	McAuley Institute, St. Mary's Hospital
Lynaugh	Kathleen	Blue Shield of California
MacMillan	Tom	Brown & Toland Medical Group
Maloney	Sheila	Santa Clara Family Health Plan
Manemann	Kevin	Sharp Community Medical Group
Mann	Scott	Sharp HealthCare
Marsh	Shawne	CalOptima
Marshall	Stephen	Sutter County Department of Human Services
Matsutsuyu	Keith	ER Connect
Mattson	Brian	Health-e-LA
Matull	Mike	Coalition of Orange County Community Clinics
McBride	Linda	County of Los Angeles
McCarthy	Kathleen	Pajaro Valley Community Health Trust
McCloud	John	IT Consultant
McEldowney	Ken	Consumer Action
McElroy	Madeline	Coalition of Orange County Community Clinics
McGlinn	Karen	Share Our Selves
McGowan	Bill	UC Davis Medical Center
McNabb	Joanne	California Department of Consumer Affairs
Meyer	Melanie	Planned Parenthood Mar Monte
Minch	David	John Muir Health
Mitchell	Lynn	Marin Medical Practice Concepts
Mitchell	Dana	California Assembly
Moore	Lee Ann	Talbert Medical Group
Murphy	Paul	Santa Clara Family Health Plan
Namkung, MD	Poki	Santa Cruz County
Nicol, FNP, PA	Annie	Petaluma Health Clinic
Nix, MHA, CHSP	Michelle	Palo Alto & Santa Cruz Medical Foundations
Nocita	Steve	Yolo County Counsel's Office
Norby	Eric	4th District Supervisor
O'Flynn	Austin	Catholic Healthcare West
Ohman	Christopher	California Association of Health Plans
Oliver	Errol	Blue Shield of California
Otake, JD	Ray	Community Health Care Network
Paes	Cynthia	Health and Human Services Agency
Patel	Jasmin	Talbert Medical Group
Payne	Mary Kay	Hoag Hospital
Peloquin	Joseph	Consolidated Tribal Health Project, Inc.
Penney	Susan	California Medical Association
Phelan	John	Institute for Community Pharmacy

LAST	FIRST	ORGANIZATION
Phillips	Jamie	Healthcare Partners
Portugal	Don	Information Services UCSD
Powe	Lynn	Aetna
Prendergast	Robin	Cedars-Sinai Medical Center
Puentes	Julie	Hospital Association of Southern California
Ralston, MD	Michael	Kaiser Permanente, Northern California
Regalado	Martin	Scan Health Plan
Reis	Ray	Sacramento County Department of Health and Human Services
Revele	Michele	CA Chapter of the American College of Emergency Physicians & Society of Orange County Emergency Physicians
Richmond	Fred	Coalition of Orange County Community Clinics
Rideout, MD	Jeff	Cisco Systems
Righetti	Lisa	Paradise Valley Hospital
Rosenthal	John	LA Care Health Plan
Ross	Will	Mendocino Informatics
Rubenstein	Richard	San Francisco Health Plan
Rushton, MD	Robert	Primary Care Physician
Ryser	Vonnie	Department of Mental Health
Sachs	Robert	Committee on the Shelterless
Samuelson	Allen	Kaiser Foundation Health Plan
Scuri	Anita	California Department of Consumer Affairs
Sgouros	Alexis	Kaiser Permanente
Siegmund	Lori	Consultant
Silber	Ralph	Community Health Care Network
Skullr	Ann Marie	MemorialCare Health Systems
Sleigh	Debra A.	Sutter Health Information Technology
Solomon	Gerry	PHFE Management Solutions, CEO
Solomon	Glen	County of Los Angeles
Solomon	Cynthia	MiVIA
Spiritus	Eugene	UC Irvine Medical Center
Spooner	Bill	CIO, Sharp HealthCare
Stansbury	Jett	Alameda Alliance for Health
Steen	Charles	Catholic Healthcare West
Steineckert	Brent	Sharp Rees-Stealy/Mission Park Medical Centers
Street	Mark	Alliance Medical Center
Stuart	Stephen	CalOHI
Sujansky, MD	Walter	Sujansky & Associates
Swetnam	Bob	Santa Cruz County
Tanner	John	SCAN Health Plan
Thomas	Sandra	LA County Department of Mental Health
Tobia	Paul	Sharp HealthCare

LAST	FIRST	ORGANIZATION
Traube	Joseph	Scripps Health
Trotter	Marvin	Mendocino City Dept Public Health
Trujillo	Alice	California Department of Alcohol and Drug Programs
Vanderpool	Lee	Dominican Santa Cruz Hospital
Ward	Roberta	California Department of Health Services
Webb	Phyllis	Mendocino City. Dept Public Health
Wenneson	Greg	Alliance for Rural Community Health
Williams	Laura	Sacramento County Department of Health and Human Services
Winterrowd	Dana	California Department of Consumer Affairs
Woods	Chris	Sutter Health
Yellowlees	Peter	UC Davis Medical Center
Young, RPh	Kim	Plott Family Care Centers
Zevnik	Timothy	Molina Healthcare

8 APPENDIX B

Regional Health Information Organization Efforts in California

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
Riverside Regional Health www.riversidehealth.blogspot.com	1	TBD	RHIO Entity: TBD		Community Riverside and San Bernardino counties in the Inland Empire	TBD	Quality of care Efficiency of Care Access
CAPG	2	Initial funding: Stakeholder contribution Ongoing funding: Subscription fees	IPA/Medical Group Entity: 510(c)(3) Professional association comprised of 149 of California's leading physician groups.	Clinical data repository for benchmarking, reporting and point of care support. Create a single data platform of pharmacy, laboratory and encounter data that will allow benchmark comparison reports and ad hoc member-generated analyses. Future vision is to migrate to a real-time data exchange for participants. Streamline and automate data submission, cleaning, matching, and analysis across disparate clinical electronic databases; Enable better clinical quality decision-making at both the	State: 13 million Californians More than 40% of California's health care is delivered by physicians employed by or contracted with CAPG members.		Need for accurate, timely patient profiles based on data successfully linked across databases Benchmarked data Need for quality data to succeed at pay for performance

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
				individual patient and population level; Support management to streamline operations and identify savings opportunities; Promote trend toward use of clinical data at the point of care; Special studies			
Greater Valley	2	Initial funding: Each participating hospital to supply own funding	Hospital Entity: Unstructured coalition	This is a hospital CIO-driven initiative primarily focused on alleviating ED patient wait-times through expedited quality care.	TBD: Primarily San Gabriel Vallen and immediate adjacent areas	ED Linking Medication management	Quality of care Access
OCPRHIO	2	Initial funding from stakeholder contributions (in-kind services). Group plans to seek grant funding.	Multiple stakeholder 510(c)(3) COCCC		Community; Orange County		To position county to respond to environmental pressure to participate in HIEs and eventually the NHIN
Alliance for Rural Community Health HIE	3	Initial funding: Grant	RHIO Managed by the Alliance for Rural Community Health	Three-year project to improve health outcomes and reduce costs associated with caring for uninsured chronic disease patients accessing multiple healthcare sites in Mendocino County through increased	Community: Mendocino County	Community results portal Chronic disease management system Registry	Efficiency of care Quality of care Access

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
			510(c)(3)	programmatic collaboration and the implementation of a virtual case management system.			
Smart Health www.jointventure.org/programs-initiatives/smartvalley/smartvalley.html	3	Initial funding: Grant and stakeholder contribution. Ongoing funding TBD with stakeholder contribution.	Multiple stakeholder task force Entity: 510(c)(3)	Inter-connect the healthcare system in Silicon Valley to facilitate the electronic exchange of patient and administrative records. Develop sustainable funding model, choose technologies and facilitate the negotiation of agreements.	Community: Silicon Valley	ePrescribing Lab orders and results reporting	Efficiency of care Quality of care Patient safety
CalRHIO	3						
Long Beach	3	Initial funding from the City of Long Beach (Bioterrorism) and PHFE Management Ongoing Funding: Unihealth foundation, PHFE, and City of Long Beach in-kind contributions.	Multiple stakeholder with a Steering Committee. Entity: 510(c)(3)	Long Beach Network for Health is committed to achieve consumer-centric and information-rich healthcare through creative and dynamic processes that will foster regional collaboration to; continuously optimize population health and quality of life by the implementation and maintenance of standardized interoperable community-wide health information infrastructure. Develop a community-wide Electronic Health Record System that will enable health care organizations to work together	Community: Long Beach	In development	Improved quality of care Disease Management Biosurveillance

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
				in the region with a unified goal of optimizing clinical outcomes.			
San Diego MINE	3		Foundation Entity: 510(c)(3) SD County Medical Society Foundation	Find a common ground, business merit and technical model for information sharing. Initial priorities: ED data information share, diabetes registry, Integrate immunization registry, clinical decision support and admin efficiency	Community: San Diego County or subset		Quality of care
Mendocino SHARE	3	Initial funding: Grant	RHIO Managed by the Alliance for Rural Community Health Entity: 510(c)(3)	Three-year project to improve health outcomes and reduce costs associated with caring for uninsured chronic disease patients accessing multiple healthcare sites in Mendocino County through increased programmatic collaboration and the implementation of a virtual case management system.	Community: Mendocino County	Community results portal Chronic disease management system Registry	Efficiency of care Quality of care Access
Health-e-LA	3	Initial funding: Unknown Ongoing funding: TBD	Multiple stakeholder Entity: Unknown	The mission of Health-e-LA is to foster the development of an infrastructure for multi-organizational electronic exchange of clinical healthcare information throughout the greater Los Angeles region. Through an inclusive approach, with public and private sector	Community: Los Angeles	Personal Health Record TBD	Efficiency of care

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
				participants, Health-e-LA envisions a future in which the electronic exchange of patient-controlled health records for residents of the Los Angeles region is seamless, easy, and secure, no matter where the person accesses healthcare.			
Northern Sierra Rural Health Network www.nsrhn.org	3	Initial funding: Grant Ongoing funding: Subscription fees	Multiple stakeholder Board of Directors with diverse membership Entity: 510(c)(3) in operation since 1996.	The mission of Northern Sierra Rural Health Network (NSRHN) is to promote the health and well-being of residents in rural Northeastern California through comprehensive health planning, educational services, integrated health care delivery systems and supporting programs and services that expand access to all residents regardless of ability to pay for healthcare. Technology programs focus on providing resources, support and connectivity to over 40 rural health providers to ensure that they are able to access the benefits of advanced e-health technology for their patients who live in the most remote and rural parts of California.	Community: Nine rural counties covering 30,000 square miles (Nevada, Sierra, Plumas, Lassen, Modoc, Shasta, Siskiyou, Trinity, Tehama)	EHR (outpatient) Practice management system Lab orders and results reporting	Access
East Kern County	4	Initial funding: Grant	RHIO/SNO	Providing enhanced quality of patient care and patient-	Community: South East Kern County	Ambulatory HER, PHR, RX interfaces,	Quality of care Access to

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
Integrated Technology Association www.ekcita.org		Ongoing funding: Stakeholder contribution/ Grant		centered care throughout transitions of care via health information exchange		lab interfaces, ADT, and ER	information Patient safety Accurate reporting
Loma Linda	4	Initial funding: California Telemedicine and eHealth Center grant	Non-profit Academic Health Science Center Entity: 510(c)(3)	Expand strategic relationships with Department of Defense, State of California, rural hospitals and clinics for providing enhanced access to specialty care for medically underserved communities; Build and implement a regional network from the existing telemedicine hub for the provision of specialty support for clinical diagnosis and treatment; Develop continuing medical education programs and curricula revisions for health career schools at LLU (Medicine, Dentistry, Nursing, Pharmacy, Allied Health, Science & Technology and Public Health); Conduct research on the impact of tele-health systems on provider and consumer acceptance; Provide support to the	Community: Urban, semi-urban and rural communities in the Inland Empire	Telemedicine connectivity	Improved access to specialty care Enhanced provider productivity Sustainability

Initiative	Stage	Funding	Governance Structure	Objectives	Scope	Project Type	Key Business Issues
				worldwide health care network sponsored by the Adventist care delivery systems.			
Santa Cruz: CCCN	4		Governance structure: RHIO 510(c)(3)	The Santa Cruz County Diabetes Mellitus Registry Project, now called the Community Chronic Care Network (CCCN), builds on a history of productive collaboration among the County's public, private, and not-for-profit health sectors. The objective of the three-year (10/04 to 9/07) AHRQ-funded project is to adapt an internet-based diabetes registry developed and used by a local IPA for community-wide use.	Community: Santa Cruz County		Quality of care Efficency of care Access
Marin Medical Practice Concepts www.mmpcinc.com	6	Initial Funding: Investment from MMPC, Inc. Ongoing funding: Monthly subscription fees from participating providers	Governance structure: MSO For profit C Corporation	Comprehensive community based EHR for private non-foundation, non-medical group users.	Community: Primarily Marin County with small presence in Sonoma	EHR (outpatient)	Access Quality of care

State Government Health Information Exchange Efforts

Department	Project Name	Goals and Objectives	Stage
Health Services	Electronic Laboratory Reporting System (ELR)	▪ Provide automated means of lab reporting and notification with a single statewide lab reporting system. ▪ Create secure environment for confidential medical information to reside, restricting access to data for reporting purposes. ▪ Reduce elapsed time to collect data from local health departments. ▪ Enable sharing of data across local health departments, public health programs and business functions.	Stage 3: Planning & Development
Health Services	MMA Part D	Automated system to allow for movement of beneficiaries from Medi-Cal to Medicare Part D for pharmaceuticals.	Stage 4: Implementing
Justice	Interstate Prescription History Information (IJIS)	▪ Pilot project sharing patient prescription information between California and Nevada. ▪ Sharing information between border states to ensure appropriate patient care.	Stage 4: Implementing
Justice	Patient Activity Report (PAR)	Automate the current manual process of providing patient prescription history to doctors.	Stage 3: Planning & Development
Mental Health	Health Information Exchange and Electronic Health Records	▪ Reports in real-time; service and billing/claiming information, assessment, correspondence, treatment planning, charting, medications, outcomes, referrals. ▪ Functions as a multi-user, multi-disciplinary, multi-functional, and multi-modal (multiple types of information, including text, images, etc) enterprise. ▪ Allows clients, providers, caregivers, and as others appropriate to enter and receive information.	Stage 3: Planning & Development

Department	Project Name	Goals and Objectives	Stage
Mental Health	Pharmacy Hospital Operations	▪ Processes medication orders and recurring non-medication orders. ▪ Generates monthly Physician Orders for renewal and information that supports unit-dose order filling functions; this includes pick lists, Medication Administration Record forms and an electronic file for the Baxter automated unit-dose dispensing machine. ▪ Checks all medication orders for Drug-to-Drug Interactions, allergies, over maximum-dose, and approval for non-formulary items. ▪ Makes medication orders visible when a patient is transferred to the new hospital and may be utilized by the new physician as baseline current medications for the new episode.	Stage 5: Fully Operational
Mental Health	Physicians' Orders System	▪ Automates physician order entry and transmission of physicians' orders to the service provider ▪ Reduces order turnaround time and errors, and promotes more timely and effective patient treatment	Stage 5: Fully Operational

9 APPENDIX C

Best Practices Found in California

RIGHTS AND RESPONSIBILITIES
• Based on their interpretations of State and federal laws, stakeholders stated that their organizations do not engage in the unauthorized release of information for research or program oversights as specified in scenario 18 (i.e. lead poisoning).
• One provider reported that only payers identified by the patient have authorized access to the medical record system, and payers' access is limited to specific documents.
• One provider uses a form to identify exactly what information the patient wants released.
• A medical foundation receives all the data requests which involve EPHI via an electronic form on the Intranet. The requests are automatically distributed to appropriate committee members with notifications to review. A committee was established to approve or deny all requests for information before disclosures are made. This review also includes EPHI reports which are to remain inside the foundation.
• State government and public health agencies, while not HIPAA covered entities, consistently practice policies and procedures that avoid using a patient's name and instead rely on descriptors. For example, if a patient visits a public health agency for counseling, that information is excluded from appearing in the patient's record for his or her regular doctor, unless otherwise instructed by the patient.
• One provider limits physicians' access only to outside provider's systems that have audit capabilities.
• One provider limits access for research purposes to requests with IRB approval and does not utilize the other HIPAA allowed disclosures for research. They conduct stringent reviews where applicable.
• Hospitals commonly do not allow others to access their systems, rather they receive requests for information and push the information out to a secure server to which the requestor has access.
• UCLA created and uses software containing an algorithm that identifies and obscures specific information within a patient's record, even within an individual image.
• One provider proactively monitors audit records per HIPAA, and adds certain identifiers into the search criteria. The provider follows up with sanctions on employees where appropriate. One identifier could be the relationship between patients and employees; for example, if an employee lives on the same street as a patient, the employee's access to the neighbor's records is proactively monitored.
• One provider parceled out data to authenticated requestors according to the type (role) of requestor; researchers, public health officials, etc. may be granted different levels of access.
• One provider tracks the details of each "break the glass" access. In a "break the glass" access, sensitive data that is not generally available to a physician is deemed necessary and

RIGHTS AND RESPONSIBILITIES
accessed for emergency treatment.
• One provider uses a public key infrastructure (PKI) to protect all data in transit between entities.

LACK OF TRUST
• One provider tracks patient record disclosures by printing the user name on the bottom of all EMR printouts.
• One hospital addresses employer requests for information by requiring the patient to sign an authorization to release information to the employer before it can be released. Depending on the patient's preference, the information may be released to the patient or may be faxed to the employer.

10 APPENDIX D

Legal Cites Related to the 18 Scenarios

The following are some of the background information used to analyze and support the legal implication findings for each scenario as presented in the Interim Assessment of Variations Report. This background information does not necessarily represent a complete legal analysis of all state and federal laws which may pertain to the RTI scenarios.

Scenario 1	**The emergent transfer of health information between two healthcare providers when the status of the patient is unsure.** Patient X presents to emergency room of General Hospital in CA. She has been in a serious car accident. The patient is an 89 year old widow who appears very confused. Law enforcement personnel in the emergency room investigating the accident indicate that the patient was driving. There are questions concerning her possible impairment due to medications. Her adult daughter informed the ER staff that her mother has recently undergone treatment at a hospital in a neighboring state and has a prescription for an antipsychotic drug. The emergency room physician determines there is a need to obtain information about Patient X's prior diagnosis and treatment during the previous inpatient stay.
Summary	An authorization may be required from the patient, or her designee, if it is required by the other state's law. Under California law, a patient is presumed to have capacity to make medical decisions (Cal. Probate Code section 810.4657). If their capacity is questioned by the physician, the authorization may be signed by an appropriate surrogate identified by the hospital, possibly the daughter (Cal. Probate Code section 4658). However, if an authorization is not required, the information necessary for treatment may be released under HIPAA [45 C.F.R. section 164.502(c)]. The emergency room physician should be able to obtain information if it is to prevent or lessen a serious or imminent threat to the health and safety of the person from the mental health records [HIPAA - 45 C.F.R. section 164.512(j)(1)(i)]) including psychotherapy note under HIPAA. If the mental health treatment the patient received in the other state was funded with federal funds, release of the information necessary for treatment would be permitted (42 C.F.R. section 2.20). If Provider number 1 is a mental health provider (as defined in California law citation needed here) then the records would also be subject to California's primary mental health record statute, the Lanterman, Petris Short Act (LPS, Welfare and Institutions Code 5328). Under the LPS [Welfare and Institutions Code section 5328], these records may fall into one of the six divisions that list records required to be confidential. The LPS definition is different from the defined medical information under the CMIA [Civil Code section 56.05(g)]. The information in the scenario may fall into this definition; identifiable information in possession of specified health care industry entities. If the provider in the scenario was a State agency, a third standard under personal information may apply (Civil Code 1798). Many other differences exist among these laws beyond what each covers, including disclosures and procedures surrounding disclosures (e.g., notices, authorizations, etc.)
	Analysis Prepared by Terri D. Keville of Manatt, Phelps & Phillips, LLP
State Law	The hospital and individual providers in the neighboring state where Patient X received

her prior inpatient treatment would be bound by that state's confidentiality of medical information laws, to the extent that such laws are more stringent than the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy regulations, and therefore not preempted by HIPAA. (HIPAA generally preempts all conflicting state laws unless they are more stringent, *i.e.*, more protective of patient privacy. 45 CFR § 160.203.) The scenario does not indicate in which state the other hospital is located. Many other states (like California) have special privacy protections for medical records that relate to mental health and/or drug abuse, so there may be state-law limitations on what information General Hospital can obtain from the other hospital, or additional requirements to be met for getting it.

The applicable HIPAA requirements, as well as federal regulations governing confidentiality of substance abuse records, are discussed below.

With respect to the issue of whether the patient has the capacity to execute any authorizations that may be required for release of the requested information, California's consent laws likely would apply to this scenario, because the patient currently is located here and her mental status would be evaluated in California.

A patient is presumed to have the capacity to make medical treatment decisions. Cal. Probate Code §§ 810, 4657. This would include decisions about release of medical information. Additionally, under Cal. Welf. & Inst. Code § 5331, "No person may be presumed to be incompetent because he or she has been evaluated or treated for a mental disorder or chronic alcoholism, regardless of whether such evaluation or treatment was voluntarily or involuntarily received."

Where, as in the scenario, the patient's capacity is questioned (because she is injured, and appears confused and possibly drug-impaired), the patient's primary physician must determine whether the patient has capacity, unless Patient X has executed an advance health care directive that specifies someone else to make this determination. Cal. Probate Code § 4658. If the patient's usual primary physician is not available (which could be the case in the scenario), then any physician who undertakes the responsibility – such as the ER physician – becomes the primary physician, who can make the capacity determination. Cal. Probate Code § 4631.

If Patient X's usual primary care physician or (if he/she is unavailable) the ER physician determines that Patient X lacks capacity, then authorization for release of medical information may be provided by an agent designated by Patient X in any written advance healthcare directive she executed while competent, or by an appropriate surrogate identified by the hospital (possibly the daughter, since Patient X is a widow and the daughter is the only family member mentioned in the scenario). *See Cobbs v. Grant*, 8 Cal. 3d 229, 244 (1972) ("if the patient is a minor or incompetent, the authority to consent is transferred to the patient's legal guardian or closest available relative").

HIPAA

A. General Use and Disclosure Principles Applicable to the Scenario

Under HIPAA, use or disclosure of protected health information (PHI) requires written patient authorization, except for purposes of treatment, payment, or health care operations. 45 C.F.R. § 164.502(a)(1)(ii); 164.506. In the scenario, the treating ER physician has determined that "there is a need to obtain information about Patient X's prior diagnosis and treatment during the previous inpatient stay." Thus, because the requested information is necessary for treatment purposes, Patient X's written authorization should not be required under HIPAA for use or disclosure of general

medical information about her out-of-state hospitalization. As discussed further below, other relevant laws that otherwise might require written authorization also contain exceptions for emergency care.

Although in many instances permissible uses and disclosure of PHI under HIPAA must be limited to the "minimum necessary" amount of information (45 C.F.R. § 164.502(b)(1)), this limitation does not apply to "[d]isclosure to or requests by a health care provider for treatment." 45 C.F.R. § 164.502(b)(2)(i).

B. Mental Health Records

Patient X's mental status is in question, and it appears that her recent out-of-state hospitalization may have been for mental health treatment (since the daughter mentioned the recent hospitalization along with the fact that Patient X was prescribed antipsychotic medication). While HIPAA generally permits disclosure of PHI for treatment purposes, HIPAA does impose a specific further restriction on use or disclosure of "psychotherapy notes," release of which requires a specific patient authorization for that purpose. 45 C.F.R. § 164.508(a)(2). "Psychotherapy notes" are defined in 45 C.F.R. § 164.501 as follows:

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of a conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

There are several enumerated exceptions to the requirement for written authorization before disclosure or use of psychotherapy notes, one of which might be applicable to the scenario. Under 45 C.F.R. § 164.508(a)(2)(ii), psychotherapy notes may be disclosed without patient authorization pursuant to 45 C.F.R. § 164.512(j)(1)(i), as "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person" where the disclosure is "to a person or persons reasonably able to prevent or lessen the threat . . . ." Patient X has been in a serious auto accident and is in the ER. If the ER physician believes there is a "serious and imminent threat" to Patient X's health and the physician cannot adequately treat Patient X without all available information regarding her prior inpatient treatment, then it would appear that the out-of-state hospital could release even psychotherapy notes to the ER physician without violating HIPAA.

If there is not a "serious and imminent threat" to Patient X's health, psychotherapy notes still could be obtained *with* Patient X's authorization, if she is determined to have capacity to make health care decisions. If she is determined to lack capacity, an appropriate surrogate could be identified and could sign the authorization.

C. Substance Abuse Treatment Records

The scenario says that, "[t]here are questions concerning [Patient X's] possible impairment due to medications." Although this most likely means Patient X may be experiencing problems due to interactions or suboptimal dosing of properly prescribed medications, it also is possible that (even at 89) Patient X could be addicted to or abusing prescription drugs, and she could have been treated for substance abuse or

dependency in the out-of-state hospital.

In that event, if the out-of-state hospital receives any federal assistance (including participation in the Medicare program), disclosure of PHI about Patient X's treatment for substance abuse there would be governed primarily by the federal statutes and regulations governing confidentiality of substance abuse treatment records (because HIPAA does not have any specific privacy regulations governing substance abuse records).

The federal drug and alcohol treatment regulations, 42 CFR §§ 2.1 – 2.67, promulgated in accordance with 42 United States Code Sections 290dd-2(g), apply to any drug or alcohol treatment program that receives any type of federal assistance, direct or indirect. A "program" includes "[a]n individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment," and "[a]n identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment." 42 CFR § 2.11. "Federal assistance" includes Medicare certification, registration to dispense drugs under the Controlled Substances Act (to the extent used in treatment), and being "supported by funds provided by any department or agency of the United states by being . . . [c]onducted by a State or local government unit which, through general or specific revenue sharing or other forms of assistance, received Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program"). 42 CFR § 2.12(b)(2)(i), (ii), (3)(ii). Therefore, if Patient's X's recent hospitalization related to substance abuse, it probably would be covered by these federal regulations.

The federal regulations prohibit disclosure of any information about drug or alcohol treatment to anyone without the patient's consent, with certain very limited exceptions. If one of the exceptions applies, then disclosure is permitted, but it is never compelled. 42 CFR § 2.3(b)(1).

Relevant to the scenario, the regulations contain a specific exception for release of substance abuse treatment records "[t]o medical personnel to the extent necessary to meet a bona fide medical emergency." 42 C.F.R. § 2.2(b)(2)(A). Since Patient X is in the ER after a serious automobile accident, and the ER physician has determined that he or she needs Patient X's prior hospitalization records to treat her in this emergency, the out-of-state hospital should be able to release them to General Hospital without Patient X's written authorization even if they are substance abuse records.

However, any disclosure that is permitted under the federal regulations governing confidentiality of substance abuse treatment records "must be limited to that information which is necessary to carry out the purpose of the disclosure." 42 CFR § 2.13(a). Also, substance abuse treatment records "must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use." 42 C.F.R. § 2.16.

Notably, like HIPAA, the federal regulations governing confidentiality of substance abuse treatment records do *not* preempt state laws that are more protective of patient privacy. 42 C.F.R. § 2.20. Therefore, if the state where the out-of-state hospital is located would require written authorization for release of the substance abuse records even in an emergency, the hospital would have to comply with that state law. Patient X or her appropriate surrogate could sign such an authorization, depending upon whether Patient X is determined to have capacity to make her own health care decisions (as discussed

above).

With respect to the interplay between the federal substance abuse regulations and HIPAA, according to the Substance Abuse and Mental Health Services Administration (SAMHSA) of the federal Department of Health and Human Services, drug abuse programs have to comply with both the federal drug and alcohol abuse regulations discussed above and HIPAA, but generally they can comply with both simply by following the federal regulations. Specifically, SAMHSA has stated as follows:

> Substance abuse treatment programs that already are complying with Part 2 should not have a difficult time complying with the Privacy Rule, as it parallels the requirements of Part 2 in many areas. Programs subject to both sets of rules must comply with both, unless there is a conflict between them. Generally, this will mean that substance abuse treatment programs should continue to follow the Part 2 regulations. In some instances, programs will have to establish new policies and procedures or alter existing policies and practices. In the event a program identifies a conflict between the rules, it should notify the Substance Abuse and Mental Health Services Administration of HHS immediately for assistance in resolving the conflict.

SAMHSA, *The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs*, p. 3 (2004). available at http://www.hipaa.samhsa.gov/Part2ComparisonCleared.htm.

Citations

State

Welfare and Institutions Code 5328:

All information and records obtained in the course of providing services under Division 4 (commencing with Section 4000), Division 4.1 (commencing with Section 4400), Division 4.5 (commencing with Section 4500), Division 5 (commencing with Section 5000), Division 6 (commencing with Section 6000), or Division 7 (commencing with Section 7100), to either voluntary or involuntary recipients of services shall be confidential. Information and records obtained in the course of providing similar services to either voluntary or involuntary recipients prior to 1969 shall also be confidential. Information and records shall be disclosed only in any of the following cases:

(a) In communications between qualified professional persons in the provision of services or appropriate referrals, or in the course of conservatorship proceedings. The consent of the patient, or his or her guardian or conservator shall be obtained before information or records may be disclosed by a professional person employed by a facility to a professional person not employed by the facility who does not have the medical or psychological responsibility for the patient's care.

(b) When the patient, with the approval of the physician, licensed psychologist, social worker with a master's degree in social work, or licensed marriage and family therapist, who is in charge of the patient, designates persons to whom information or records may be released, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family. Nothing in this subdivision shall be construed to authorize a licensed marriage and family therapist to provide services or to be in charge of a patient's care beyond his or her lawful scope of practice.

(c) To the extent necessary for a recipient to make a claim, or for a claim to be made

on behalf of a recipient for aid, insurance, or medical assistance to which he or she may be entitled.

(d) If the recipient of services is a minor, ward, or conservatee, and his or her parent, guardian, guardian ad litem, or conservator designates, in writing, persons to whom records or information may be disclosed, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(e) For research, provided that the Director of Mental Health or the Director of Developmental Services designates by regulation, rules for the conduct of research and requires the research to be first reviewed by the appropriate institutional review board or boards. The rules shall include, but need not be limited to, the requirement that all researchers shall sign an oath of confidentiality as follows:

Date _____

As a condition of doing research concerning persons who have received services from ____ (fill in the facility, agency or person), I, ____, agree to obtain the prior informed consent of such persons who have received services to the maximum degree possible as determined by the appropriate institutional review board or boards for protection of human subjects reviewing my research, and I further agree not to divulge any information obtained in the course of such research to unauthorized persons, and not to publish or otherwise make public any information regarding persons who have received services such that the person who received services is identifiable.

I recognize that the unauthorized release of confidential information may make me subject to a civil action under provisions of the Welfare and Institutions Code.

(f) To the courts, as necessary to the administration of justice.

(g) To governmental law enforcement agencies as needed for the protection of federal and state elective constitutional officers and their families.

(h) To the Committee on Senate Rules or the Committee on Assembly Rules for the purposes of legislative investigation authorized by the committee.

(i) If the recipient of services who applies for life or disability insurance designates in writing the insurer to which records or information may be disclosed.

(j) To the attorney for the patient in any and all proceedings upon presentation of a release of information signed by the patient, except that when the patient is unable to sign the release, the staff of the facility, upon satisfying itself of the identity of the attorney, and of the fact that the attorney does represent the interests of the patient, may release all information and records relating to the patient except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(k) Upon written agreement by a person previously confined in or otherwise treated by a facility, the professional person in charge of the facility or his or her designee may release any information, except information that has been given in confidence by members of the person's family, requested by a probation officer charged with the

evaluation of the person after his or her conviction of a crime if the professional person in charge of the facility determines that the information is relevant to the evaluation. The agreement shall only be operative until sentence is passed on the crime of which the person was convicted. The confidential information released pursuant to this subdivision shall be transmitted to the court separately from the probation report and shall not be placed in the probation report. The confidential information shall remain confidential except for purposes of sentencing. After sentencing, the confidential information shall be sealed.

(l) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to subdivision (d) of Section 18951. The information and records sought to be disclosed shall be relevant to the prevention, identification, management, or treatment of an abused child and his or her parents pursuant to Chapter 11 (commencing with Section 18950) of Part 6 of Division 9.

(m) To county patients' rights advocates who have been given knowing voluntary authorization by a client or a guardian ad litem. The client or guardian ad litem, whoever entered into the agreement, may revoke the authorization at any time, either in writing or by oral declaration to an approved advocate.

(n) To a committee established in compliance with Sections 4070.

(o) In providing information as described in Section 7325.5. Nothing in this subdivision shall permit the release of any information other than that described in Section 7325.5."

(p) To the county mental health director or the director's designee, or to a law enforcement officer, or to the person designated by a law enforcement agency, pursuant to Sections 5152.1 and 5250.1."

(q) If the patient gives his or her consent, information specifically pertaining to the existence of genetically handicapping conditions, as defined in Section 125135 of the Health and Safety Code, may be released to qualified professional persons for purposes of genetic counseling for blood relatives upon request of the blood relative. For purposes of this subdivision, "qualified professional persons" means those persons with the qualifications necessary to carry out the genetic counseling duties under this subdivision as determined by the genetic disease unit established in the State Department of Health Services under Section 125000 of the Health and Safety Code. If the patient does not respond or cannot respond to a request for permission to release information pursuant to this subdivision after reasonable attempts have been made over a two-week period to get a response, the information may be released upon request of the blood relative.

(r) When the patient, in the opinion of his or her psychotherapist, presents a serious danger of violence to a reasonably foreseeable victim or victims, then any of the information or records specified in this section may be released to that person or persons and to law enforcement agencies as the psychotherapist determines is needed for the protection of that person or persons. For purposes of this subdivision, "psychotherapist" means anyone so defined within Section 1010 of the Evidence Code.

(s) (1) To the designated officer of an emergency response employee, and from that designated officer to an emergency response employee regarding possible exposure to HIV or AIDS, but only to the extent necessary to comply with provisions of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(2) For purposes of this subdivision, "designated officer" and "emergency response employee" have the same meaning as these terms are used in the Ryan White

Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(3) The designated officer shall be subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV results. Further, the designated officer shall inform the exposed emergency response employee that the employee is also subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV test results. (t) (1) To a law enforcement officer who personally lodges with a facility, as defined in paragraph (2), a warrant of arrest or an abstract of such a warrant showing that the person sought is wanted for a serious felony, as defined in Section 1192.7 of the Penal Code, or a violent felony, as defined in Section 667.5 of the Penal Code. The information sought and released shall be limited to whether or not the person named in the arrest warrant is presently confined in the facility. This paragraph shall be implemented with minimum disruption to health facility operations and patients, in accordance with Section 5212. If the law enforcement officer is informed that the person named in the warrant is confined in the facility, the officer may not enter the facility to arrest the person without obtaining a valid search warrant or the permission of staff of the facility.

(2) For purposes of paragraph (1), a facility means all of the following:

(A) A state hospital, as defined in Section 4001.

(B) A general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, solely with regard to information pertaining to a mentally disordered person subject to this section.

(C) An acute psychiatric hospital, as defined in subdivision (b) of Section 1250 of the Health and Safety Code.

(D) A psychiatric health facility, as described in Section 1250.2 of the Health and Safety Code.

(E) A mental health rehabilitation center, as described in Section 5675.

(F) A skilled nursing facility with a special treatment program for chronically mentally disordered patients, as described in Sections 51335 and 72445 to 72475, inclusive, of Title 22 of the California Code of Regulations.

(u) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to Section 15610.55, 15753.5, or 15761. The information and records sought to be disclosed shall be relevant to the prevention, identification, management, or treatment of an abused elder or dependent adult pursuant to Chapter 13 (commencing with Section 15750) of Part 3 of Division 9.

(v) The amendment of subdivision (d) enacted at the 1970 Regular Session of the Legislature does not constitute a change in, but is declaratory of, the preexisting law.

(w) This section shall not be limited by Section 5150.05 or 5332.

(x) (1) When an employee is served with a notice of adverse action, as defined in Section 19570 of the Government Code, the following information and records may be released:

(A) All information and records that the appointing authority relied upon in issuing the notice of adverse action.

(B) All other information and records that are relevant to the adverse action, or that would constitute relevant evidence as defined in Section 210 of the Evidence Code.

(C) The information described in subparagraphs (A) and (B) may be released only if both of the following conditions are met:

(i) The appointing authority has provided written notice to the consumer and the consumer's legal representative or, if the consumer has no legal representative or if the legal representative is a state agency, to the clients' rights advocate, and the consumer, the consumer's legal representative, or the clients' rights advocate has not objected in writing to the appointing authority within five business days of receipt of the notice, or the appointing authority, upon review of the objection has determined that the circumstances on which the adverse action is based are egregious or threaten the health, safety, or life of the consumer or other consumers and without the information the adverse action could not be taken.

(ii) The appointing authority, the person against whom the adverse action has been taken, and the person's representative, if any, have entered into a stipulation that does all of the following:

(I) Prohibits the parties from disclosing or using the information or records for any purpose other than the proceedings for which the information or records were requested or provided.

(II) Requires the employee and the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee' s legal representative because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(III) Requires the parties to submit the stipulation to the administrative tribunal with jurisdiction over the adverse action at the earliest possible opportunity.

(2) For the purposes of this subdivision, the State Personnel Board may, prior to any appeal from adverse action being filed with it, issue a protective order, upon application by the appointing authority, for the limited purpose of prohibiting the parties from disclosing or using information or records for any purpose other than the proceeding for which the information or records were requested or provided, and to require the employee or the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final, except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee's legal representatives because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(3) Individual identifiers, including, but not limited to, names, social security numbers, and hospital numbers, that are not necessary for the prosecution or defense of the adverse action, shall not be disclosed.

(4) All records, documents, or other materials containing confidential information protected by this section that has been submitted or otherwise disclosed to the administrative agency or other person as a component of an appeal from an adverse action shall, upon proper motion by the appointing authority to the administrative tribunal,

be placed under administrative seal and shall not, thereafter, be subject to disclosure to any person or entity except upon the issuance of an order of a court of competent jurisdiction.

(5) For purposes of this subdivision, an adverse action becomes final when the employee fails to answer within the time specified in Section 19575 of the Government Code, or, after filing an answer, withdraws the appeal, or, upon exhaustion of the administrative appeal or of the judicial review remedies as otherwise provided by law.

Welfare and Institutions Code 5331: No person may be presumed to be incompetent because he or she has been evaluated or treated for mental disorder or chronic alcoholism, regardless of whether such evaluation or treatment was voluntarily or involuntarily received. Any person who leaves a public or private mental health facility following evaluation or treatment for mental disorder or chronic alcoholism, regardless of whether that evaluation or treatment was voluntarily or involuntarily received, shall be given a statement of California law as stated in this paragraph.

Any person who has been, or is, discharged from a state hospital and received voluntary or involuntary treatment under former provisions of this code relating to inebriates or the mentally ill shall, upon request to the state hospital superintendent or the State Department of Mental Health, be given a statement of California law as stated in this section unless the person is found to be incompetent under proceedings for conservatorship or guardianship.

Civil Code 56.05: 56.05. For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

"Marketing" does not include any of the following:

(1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(2) Communications made to current enrollees solely for the purpose of describing a

provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(3) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(A) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(B) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(C) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs.

"Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health

and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

Civil Code 1798: This chapter shall be known and may be cited as the Information Practices Act of 1977.

Probate Code 810*:* The Legislature finds and declares the following:

(a) For purposes of this part, there shall exist a rebuttable presumption affecting the burden of proof that all persons have the capacity to make decisions and to be responsible for their acts or decisions.

(b) A person who has a mental or physical disorder may still be capable of contracting, conveying, marrying, making medical decisions, executing wills or trusts, and performing other actions.

(c) A judicial determination that a person is totally without understanding, or is of unsound mind, or suffers from one or more mental deficits so substantial that, under the circumstances, the person should be deemed to lack the legal capacity to perform a specific act, should be based on evidence of a deficit in one or more of the person's mental functions rather than on a diagnosis of a person's mental or physical disorder.

Probate Code 4631: "Primary physician" means a physician designated by a patient or the patient's agent, conservator, or surrogate, to have primary responsibility for the patient's health care or, in the absence of a designation or if the designated physician is not reasonably available or declines to act as primary physician, a physician who undertakes the responsibility.

Probate Code 4657: A patient is presumed to have the capacity to make a health care decision, to give or revoke an advance health care directive, and to designate or disqualify a surrogate. This presumption is a presumption affecting the burden of proof.

Probate Code 4658: Unless otherwise specified in a written advance health care directive, for the purposes of this ***division***, a determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual health care instruction or the authority of an agent or surrogate, shall be made by the primary physician.

HIPAA and other federal regulations

45 CFR § 160.203§ General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under §160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare,

and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

45 C.F.R. section 164.502(c:) Uses and disclosures of protected health information: general rules.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

45 C.F.R. section 164.512(j)(1)(i):

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*.

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or…

42 CFR 2.2(b)(2)(A): Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical

emergency.

42 CFR § 2.3(b)(1): Purpose and effect.

(b) Effect. (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

42 CFR § 2.11: Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as

providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See Sec. 2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the progams, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

42 CFR § 2.12(b)(2)(i), (ii), (3)(ii): Applicability

(b) Federal assistance. An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR

291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

42 CFR 2.13(a): Confidentiality restrictions.

(a) General. The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

42 CFR 2.16: Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

42 CFR 2.20: Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

Scenario 2	**The non-emergent transfer of records from a specialty substance treatment provider to a primary care facility for a referral.** An inpatient specialty substance abuse treatment facility wants to refer client X to a primary care facility for a suspected medical problem. The two organizations do not have a previous relationship. The client has a long history of using various drugs and alcohol relevant for medical diagnosis. The requested substance abuse information is being sent to the primary care provider without the patient's authorization. The primary care provider refers the patient to a specialist and sends all of his/her information (i.e. the primary care provider collected information) (without patient authorization) including the information received from the substance abuse treatment facility to the specialist.
Summary	Written consent is required under the federal alcohol and drug confidentiality rules [42 C.F.R. Part 2.42 and 42 C.F.R. Part 2.31], to disclose information from the substance abuse provider to the primary care provider if the substance abuse treatment was federally assisted. If the previous treatment was not funded with federal monies, the disclosure would be allowed as treatment under HIPAA [45 C.F.R. section 164.502(c)] and State law [CMIA – Civil Code section 56.10(c)(1)]. The re-disclosure prohibition for the alcohol and drug information would not apply to the primary care provider's future treatment disclosures.
Analysis	1. The transfer of information from the substance abuse provider (#1) to the primary care provider (#2) requires written consent of the patient under federal alcohol and drug confidentiality rules, 42 CFR Part 2. 42 CFR 2.31 has fairly explicit requirements for a valid consent. 2. Theoretically, 42 CFR Part 2 only applies to "federally assisted" alcohol and drug programs. This is broad enough to capture almost everyone -- tax-exempt, Medicaid, Medicare are all clearly in, and most other public funds are federally tainted as well. But a perfect system would know that there could be providers not covered. California has (or had(?), I can't lay my hands on it right off) a provision in our codes stating simply that these types of records are confidential. We've never relied on it. 3. HIPAA would allow this transfer for treatment purposes, without consent, but keep reading. 4. If Provider #1 is also a part of the mental health system, such as either the facility or a treating professional having a mental health license (this occurs frequently), then the records (or part of them) would also be subject to the HIPAA rules on psychotherapy notes. CA Welfare & Institutions Code 5328 would likely also apply if the mental health threshold is crossed. 5. 42 CFR 2.32 also requires Provider #1 to notify Provider #2 in writing that redisclosure of the information to others is prohibited, so the transfer of Provider #1's records or information to another specialist (#3) requires either a new consent or that the consent for the #1 to #2 transfer be broad enough to permit redisclosure. The standard consent forms likely in use by Provider #2 will not meet the requirements of 42 CFR 2.31. 6. The redisclosure prohibition does not apply to information collected by Provider #2, since Provider #2 is not an alcohol or drug program. Under HIPAA, that information should move freely.

Citations: State

Civil Code section 56.10(c)(1): (c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

Welfare and Institutions Code section 5328: All information and records obtained in the course of providing services under Division 4 (commencing with Section 4000), Division 4.1 (commencing with Section 4400), Division 4.5 (commencing with Section 4500), Division 5 (commencing with Section 5000), Division 6 (commencing with Section 6000), or Division 7 (commencing with Section 7100), to either voluntary or involuntary recipients of services shall be confidential. Information and records obtained in the course of providing similar services to either voluntary or involuntary recipients prior to 1969 shall also be confidential. Information and records shall be disclosed only in any of the following cases:

(a) In communications between qualified professional persons in the provision of services or appropriate referrals, or in the course of conservatorship proceedings. The consent of the patient, or his or her guardian or conservator shall be obtained before information or records may be disclosed by a professional person employed by a facility to a professional person not employed by the facility who does not have the medical or psychological responsibility for the patient's care.

(b) When the patient, with the approval of the physician, licensed psychologist, social worker with a master's degree in social work, or licensed marriage and family therapist, who is in charge of the patient, designates persons to whom information or records may be released, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family. Nothing in this subdivision shall be construed to authorize a licensed marriage and family therapist to provide services or to be in charge of a patient's care beyond his or her lawful scope of practice.

(c) To the extent necessary for a recipient to make a claim, or for a claim to be made on behalf of a recipient for aid, insurance, or medical assistance to which he or she may be entitled.

(d) If the recipient of services is a minor, ward, or conservatee, and his or her parent, guardian, guardian ad litem, or conservator designates, in writing, persons to whom records or information may be disclosed, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(e) For research, provided that the Director of Mental Health or the Director of Developmental Services designates by regulation, rules for the conduct of research and

requires the research to be first reviewed by the appropriate institutional review board or boards. The rules shall include, but need not be limited to, the requirement that all researchers shall sign an oath of confidentiality as follows:

Date _____

As a condition of doing research concerning persons who have received services from ____ (fill in the facility, agency or person), I, ____, agree to obtain the prior informed consent of such persons who have received services to the maximum degree possible as determined by the appropriate institutional review board or boards for protection of human subjects reviewing my research, and I further agree not to divulge any information obtained in the course of such research to unauthorized persons, and not to publish or otherwise make public any information regarding persons who have received services such that the person who received services is identifiable.

I recognize that the unauthorized release of confidential information may make me subject to a civil action under provisions of the Welfare and Institutions Code.

(f) To the courts, as necessary to the administration of justice.

(g) To governmental law enforcement agencies as needed for the protection of federal and state elective constitutional officers and their families.

(h) To the Committee on Senate Rules or the Committee on Assembly Rules for the purposes of legislative investigation authorized by the committee.

(i) If the recipient of services who applies for life or disability insurance designates in writing the insurer to which records or information may be disclosed.

(j) To the attorney for the patient in any and all proceedings upon presentation of a release of information signed by the patient, except that when the patient is unable to sign the release, the staff of the facility, upon satisfying itself of the identity of the attorney, and of the fact that the attorney does represent the interests of the patient, may release all information and records relating to the patient except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(k) Upon written agreement by a person previously confined in or otherwise treated by a facility, the professional person in charge of the facility or his or her designee may release any information, except information that has been given in confidence by members of the person's family, requested by a probation officer charged with the evaluation of the person after his or her conviction of a crime if the professional person in charge of the facility determines that the information is relevant to the evaluation. The agreement shall only be operative until sentence is passed on the crime of which the person was convicted. The confidential information released pursuant to this subdivision shall be transmitted to the court separately from the probation report and shall not be placed in the probation report. The confidential information shall remain confidential except for purposes of sentencing. After sentencing, the confidential information shall be sealed.

(l) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to subdivision (d) of Section 18951. The information and records sought to be disclosed shall be relevant to the prevention, identification,

management, or treatment of an abused child and his or her parents pursuant to Chapter 11 (commencing with Section 18950) of Part 6 of Division 9.

(m) To county patients' rights advocates who have been given knowing voluntary authorization by a client or a guardian ad litem. The client or guardian ad litem, whoever entered into the agreement, may revoke the authorization at any time, either in writing or by oral declaration to an approved advocate.

(n) To a committee established in compliance with Sections 4070.

(o) In providing information as described in Section 7325.5. Nothing in this subdivision shall permit the release of any information other than that described in Section 7325.5."

(p) To the county mental health director or the director's designee, or to a law enforcement officer, or to the person designated by a law enforcement agency, pursuant to Sections 5152.1 and 5250.1."

(q) If the patient gives his or her consent, information specifically pertaining to the existence of genetically handicapping conditions, as defined in Section 125135 of the Health and Safety Code, may be released to qualified professional persons for purposes of genetic counseling for blood relatives upon request of the blood relative. For purposes of this subdivision, "qualified professional persons" means those persons with the qualifications necessary to carry out the genetic counseling duties under this subdivision as determined by the genetic disease unit established in the State Department of Health Services under Section 125000 of the Health and Safety Code. If the patient does not respond or cannot respond to a request for permission to release information pursuant to this subdivision after reasonable attempts have been made over a two-week period to get a response, the information may be released upon request of the blood relative.

(r) When the patient, in the opinion of his or her psychotherapist, presents a serious danger of violence to a reasonably foreseeable victim or victims, then any of the information or records specified in this section may be released to that person or persons and to law enforcement agencies as the psychotherapist determines is needed for the protection of that person or persons. For purposes of this subdivision, "psychotherapist" means anyone so defined within Section 1010 of the Evidence Code.

(s) (1) To the designated officer of an emergency response employee, and from that designated officer to an emergency response employee regarding possible exposure to HIV or AIDS, but only to the extent necessary to comply with provisions of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(2) For purposes of this subdivision, "designated officer" and "emergency response employee" have the same meaning as these terms are used in the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(3) The designated officer shall be subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV results. Further, the designated officer shall inform the exposed emergency response employee that the employee is also subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV test results.

(t) (1) To a law enforcement officer who personally lodges with a facility, as defined in paragraph (2), a warrant of arrest or an abstract of such a warrant showing that the person sought is wanted for a serious felony, as defined in Section 1192.7 of the Penal

Code, or a violent felony, as defined in Section 667.5 of the Penal Code. The information sought and released shall be limited to whether or not the person named in the arrest warrant is presently confined in the facility. This paragraph shall be implemented with minimum disruption to health facility operations and patients, in accordance with Section 5212. If the law enforcement officer is informed that the person named in the warrant is confined in the facility, the officer may not enter the facility to arrest the person without obtaining a valid search warrant or the permission of staff of the facility.

(2) For purposes of paragraph (1), a facility means all of the following:

(A) A state hospital, as defined in Section 4001.

(B) A general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, solely with regard to information pertaining to a mentally disordered person subject to this section.

(C) An acute psychiatric hospital, as defined in subdivision (b) of Section 1250 of the Health and Safety Code.

(D) A psychiatric health facility, as described in Section 1250.2 of the Health and Safety Code.

(E) A mental health rehabilitation center, as described in Section 5675.

(F) A skilled nursing facility with a special treatment program for chronically mentally disordered patients, as described in Sections 51335 and 72445 to 72475, inclusive, of Title 22 of the California Code of Regulations.

(u) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to Section 15610.55, 15753.5, or 15761. The information and records sought to be disclosed shall be relevant to the prevention, identification, management, or treatment of an abused elder or dependent adult pursuant to Chapter 13 (commencing with Section 15750) of Part 3 of Division 9.

(v) The amendment of subdivision (d) enacted at the 1970 Regular Session of the Legislature does not constitute a change in, but is declaratory of, the preexisting law.

(w) This section shall not be limited by Section 5150.05 or 5332.

(x) (1) When an employee is served with a notice of adverse action, as defined in Section 19570 of the Government Code, the following information and records may be released:

(A) All information and records that the appointing authority relied upon in issuing the notice of adverse action.

(B) All other information and records that are relevant to the adverse action, or that would constitute relevant evidence as defined in Section 210 of the Evidence Code.

(C) The information described in subparagraphs (A) and (B) may be released only if both of the following conditions are met:

(i) The appointing authority has provided written notice to the consumer and the consumer's legal representative or, if the consumer has no legal representative or if the legal representative is a state agency, to the clients' rights advocate, and the consumer, the consumer's legal representative, or the clients' rights advocate has not objected in writing to the appointing authority within five business days of receipt of the notice, or the appointing authority, upon review of the objection has determined that the circumstances on which the adverse action is based are egregious or threaten the health, safety, or life of the consumer or other consumers and without the information the adverse action

could not be taken.

(ii) The appointing authority, the person against whom the adverse action has been taken, and the person's representative, if any, have entered into a stipulation that does all of the following:

(I) Prohibits the parties from disclosing or using the information or records for any purpose other than the proceedings for which the information or records were requested or provided.

(II) Requires the employee and the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee' s legal representative because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(III) Requires the parties to submit the stipulation to the administrative tribunal with jurisdiction over the adverse action at the earliest possible opportunity.

(2) For the purposes of this subdivision, the State Personnel Board may, prior to any appeal from adverse action being filed with it, issue a protective order, upon application by the appointing authority, for the limited purpose of prohibiting the parties from disclosing or using information or records for any purpose other than the proceeding for which the information or records were requested or provided, and to require the employee or the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final, except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee's legal representatives because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(3) Individual identifiers, including, but not limited to, names, social security numbers, and hospital numbers, that are not necessary for the prosecution or defense of the adverse action, shall not be disclosed.

(4) All records, documents, or other materials containing confidential information protected by this section that has been submitted or otherwise disclosed to the administrative agency or other person as a component of an appeal from an adverse action shall, upon proper motion by the appointing authority to the administrative tribunal, be placed under administrative seal and shall not, thereafter, be subject to disclosure to any person or entity except upon the issuance of an order of a court of competent jurisdiction.

(5) For purposes of this subdivision, an adverse action becomes final when the employee fails to answer within the time specified in Section 19575 of the Government Code, or, after filing an answer, withdraws the appeal, or, upon exhaustion of the administrative appeal or of the judicial review remedies as otherwise provided by law.

HIPAA and other federal regulations

42 C.F.R. section 2.31: Form of written consent.

(a) Required elements. A written consent to a disclosure under these regulations must

include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under Sec. 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under Sec. 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) Sample consent form. The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) Request Authorize:

2. (name or general designation of program which is to make the disclosure)

_____

3. To disclose: (kind and amount of information to be disclosed)

_____

4. To: (name or title of the person or organization to which disclosure is to be made)

_____

5. For (purpose of the disclosure)

_____

6. Date (on which this consent is signed)

_____

7. Signature of patient

_____

8. Signature of parent or guardian (where required)

_____

9. Signature of person authorized to sign in lieu of the patient (where required)

_____

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) Expired, deficient, or false consent. A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

42 CFR Part 2.32: Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

45 C.F.R. section 164.502(c) Uses and disclosures of protected health information: general rules.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

Scenario 3	**Patient Care, Skilled Nursing Facility** 5:30pm: Dr. X, a psychiatrist, arrives at the skilled nursing facility to evaluate his patient, recently discharged from the hospital psych unit to the nursing home. The hospital and skilled nursing facility are separate entities and do not share electronic record systems. At the time of the patient's transfer, the discharge summary and other pertinent records and forms were electronically transmitted to the skilled nursing home. Upon entering the facility Dr. X seeks assistance in locating his patient, gaining entrance to the locked psych unit and accessing her electronic health record to review her discharge summary, I&O, MAR and progress notes. Dr. X was able to enter the unit by showing a picture identification badge, but was not able to access the EHR. As it is Dr. X's first visit, he has no login or password to use their system. Dr. X completes his visit and prepares to complete his documentation for the nursing home. Unable to access the skilled nursing facility EHR, Dr. X dictates his initial assessment via telephone to his outsourced, offshore transcription service. The assessment is transcribed and posted to a secure web portal. The next morning, from his home computer, Dr. X checks his e-mail and receives notification that the assessment is available. Dr. X logs into his office web portal, reviews the assessment, and applies his electronic signature. Later that day, Dr X's Office Manager downloads this assessment from the web portal, saves the document in the patient's record in his office and forwards the now encrypted document to the long-term care facility via e-mail. The skilled nursing facility notifies Dr. X's office that they are unable to open the encrypted document because they do not have the encryption key.
Summary	Simply trying to determine applicability of the CMIA (Civil Code section 56) to each of the individuals and entities requires different interpretations for each. Often one section will cross-reference to another section. The transcription service involved in Scenario 3 would likely be a business associate of the psychiatrist [HIPAA – 45 C.F.R. section 164.504(e)], therefore requiring the transcription service comply with the HIPAA business associate standards.
State Laws	Psychiatric hospital, psychiatrist, SNF and contractors all covered by the CMIA: Civil Code section 56.05(j) of the Confidentiality of Medical Information Act (CMIA) defines "provider of health care" as meaning "any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. . . ." Civil Code section 56.05(j) of the CMIA defines "provider of health care" as meaning (among other persons and entities), ". . . any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code." Pursuant to Health and Safety Code section 1250(c), "skilled nursing facilities" are health facilities licensed pursuant to Division 2 of the Health and Safety Code, and are thus covered by the CMIA." Civil Code section 56.05(c) of the CMIA defines "contractor" to mean (in relevant part) "any person or entity that is a medical group, independent practice association,

pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care."

Disclosure laws:

Civil Code Section 56.10(c)(1) of the CMIA provides as follows:

"(c) A provider of health care, or a health care service plan may disclose medical information [without authorization from the individual] as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code."

Civil Code Section 56.104 of the CMIA provides as follows:

"(a) Notwithstanding subdivision (c) of Section 56.10, except as authorized by paragraph (1) of subdivision (c), of Section 56.10, no provider of health care, health care service plan, or contractor may release medical information to persons or entities authorized by law to receive that information pursuant to subdivision (c) of Section 56.10, if the requested information specifically relates to the patient's participation in outpatient treatment with a psychotherapist, unless the person or entity requesting that information submits to the patient pursuant to subdivision (b) and to the provider of health care, health care service plan, or contractor a written request, signed by the person requesting the information or an authorized agent of the entity requesting the information, that includes all of the following:

(1) The specific information relating to a patient's participation in outpatient treatment with a psychotherapist being requested and its specific intended use or uses.

(2) The length of time during which the information will be kept before being destroyed or disposed of. A person or entity may extend that timeframe, provided that the person or entity notifies the provider, plan, or contractor of the extension. Any notification of an extension shall include the specific reason for the extension, the intended use or uses of the information during the extended time, and the expected date of the destruction of the information.

(3) A statement that the information will not be used for any purpose other than its intended use.

(4) A statement that the person or entity requesting the information will destroy the information and all copies in the person' s or entity's possession or control, will cause it to be destroyed, or will return the information and all copies of it before or immediately after the length of time specified in paragraph (2) has expired.

(b) The person or entity requesting the information shall submit a copy of the written request required by this section to the patient within 30 days of receipt of the information requested, unless the patient has signed a written waiver in the form of a letter signed and submitted by the patient to the provider of health care or health

care service plan waiving notification.

(c) For purposes of this section, "psychotherapist" means a person who is both a "psychotherapist" as defined in Section 1010 of the Evidence Code and a "provider of health care" as defined in subdivision (i) of Section 56.05 of the Civil Code. […]

(e) Nothing in this section shall be construed to grant any additional authority to a provider of health care, health care service plan, or contractor to disclose information to a person or entity without the patient's consent."

Civil Code Section 56.10(c)(1) of the CMIA is preempted by HIPAA. The statute is contrary to HIPAA for the following reasons:

- Pursuant to HIPAA section 164.506(c), a covered entity is permitted to disclose protected health information for treatment purposes regardless of to whom the disclosure is made. Section 56.10(c)(1), on the other hand, limits to whom such disclosures may be made to "providers of health care, health care service plans, contractors, or other health care professionals or facilities; and
- Pursuant to HIPAA, there are no permitted *disclosures* of "psychotherapy notes" for purposes of treatment, which is not the case in Section 56.10(c)(1). Under HIPAA, a covered entity may not disclose psychotherapy notes for purposes of its own treatment operations or another covered entity's treatment operations without first obtaining an authorization from the individual who is the subject of the protected health information. (45 C.F.R. § 164.508(a)(2)).) However, the drafter of the psychotherapy notes may use the psychotherapy notes—without first obtaining an authorization from the individual who is the subject of the protected health information—for his/her own use for treatment.] [NOTE: Section 56.10(c)(1) allows for disclosures for "diagnosis" in addition to "treatment". And although the definition of "treatment" in HIPAA does not expressly include "diagnosis," we believe it nonetheless fits the description of "treatment" in HIPAA and is not therefore, in this respect, contrary to HIPAA.]

Civil Code Section 56.104 of the CMIA is not preempted by HIPAA. Civil Code Section 56.104 does not itself permit the disclosure of mental health information. Instead, it requires that certain notifications and representations be made in writing to the patient whose out-patient psychotherapy information has already been disclosed. Since HIPAA has no analogous notification provisions, Civil Code Section 56.104 cannot be contrary to HIPAA and thus subject to preemption.

HIPAA Rules

HIPAA permits use or disclosure of PHI for treatment purposes as follows: [45 C.F.R. § 164.506]

- A covered entity may **use** or disclose PHI for its **own treatment,** payment, or health care operations.
- A covered entity may **disclose** PHI for **treatment** activities of a health care provider.

Minimum necessary does not apply to treatment activities.

HIPAA defines treatment as providing, coordinating or managing health care and related services by one or more health care providers, including:

- o Coordinating or managing health care by a health care provider with a third party;

- Consultation between health care providers relating to a patient; or

The referral of a patient for health care from one health care provider to another. [45 C.F.R. § 164.501, definition of treatment.]

Scenario 4	**Patient Care, Cancer Screening; The non-emergent transfer of health information** Patient X is HIV positive and is having a complete physical at General Hospital and an outpatient mammogram done in the Women's Imaging Center of General Hospital in CA. She had her last physical and mammogram in an outpatient clinic in Oregon. Her CA is requesting a copy of her complete records. The radiologist at the Women's Imaging Center of General Hospital would like to review the digital images of the mammogram performed at the outpatient clinic in Oregon for comparison purposes. She also is having a test for the BrCa gene and is requesting the genetic test results of her deceased aunt who had a history of breast cancer.
Summary	The law that would apply to this scenario is relatively new and the regulations providing guidance for implementation are not yet promulgated. The California Department of Health Services has issued temporary instructions stating if the HIV test was conducted prior to the implementation date of the new provision, then a provider cannot report the information without patient consent. However, if the test was conducted after the date of the new law, the provider can report the information.
State Laws	Health and Safety Code section 120985 provides as follows: "(a) Notwithstanding Section 120980, the results of an HIV test that identifies or provides identifying characteristics of the person to whom the test results apply may be recorded by the physician who ordered the test in the test subject's medical record or otherwise disclosed without written authorization of the subject of the test, or the subject's representative as set forth in Section 121020, to the test subject's providers of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, for purposes of diagnosis, care, or treatment of the patient, except that for purposes of this section "providers of health care" does not include a health care service plan regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2. (b) Recording or disclosure of HIV test results pursuant to subdivision (a) does not authorize further disclosure unless otherwise permitted by law." Health and Safety Code section 121010 provides as follows: "Notwithstanding Section 120975 or 120980, the results of a blood test to detect antibodies to the probable causative agent of AIDS may be disclosed to any of the following persons without written authorization of the subject of the test: . . . (b) To a test subject's provider of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, except that for purposes of this section, "provider of health care" does not include a health care service plan regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2. (c) To an agent or employee of the test subject's provider of health care who provides direct patient care and treatment . . . ." Pursuant to these State laws, it appears that the uses and disclosures contemplated in the scenario would be legally appropriate.
HIPAA	The foregoing State laws are not preempted by HIPAA. With respect to Health and Safety Code section 120985, it mandates the following two restrictions that make it "more

stringent" than HIPAA standards:

- Excepts as "providers of health care" health care service plans regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2.
- Provides that recording or disclosure of HIV test results pursuant to does not authorize further disclosure unless otherwise permitted by law.

Although HIPAA permits use and disclosure of PHI for treatment purposes [45 C.F.R. § 164.506], HIPAA does not provide these restrictions. Health and Safety Code section 121010 is more stringent than HIPAA because it contains a restriction that HIPAA does not:

- Excepts as "providers of health care" health care service plans regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2.

Accordingly, HIPAA has no impact on these State laws and they could be followed exclusively.

HIPAA rules:

[NOTE: HIPAA is Inapplicable because it does not preempt State law in this instance.]

Scenario 5	**Payment, Payer Access to EHR** Health Payer X (third party, disability insurance, employee assistance programs) provides health insurance coverage to many subscribers in the region which the healthcare provider serves. As part of the insurance coverage, it is necessary for the health plan case managers to approve/authorize all inpatient encounters. This requires access to the patient health information (e.g., emergency department records, clinic notes, etc.). The health care provider has recently implemented an electronic health record (EHR) system. All patient information is now maintained in the EHR and is accessible to users who have been granted access through an approval process. Access to the EHR has been restricted to the healthcare provider's workforce members and medical staff members and their office staff. Health Payer X is requesting access to the EHR for their accredited case management staff to approve/authorize inpatient encounters.
Summary	In this scenario, State law allows a provider or plan to disclose medical information to the extent necessary to determine or make payment (CMIA – Civil Code section 56.10(c)(2)]. This similar standard is not identical to HIPAA's standard [45 C.F.R. section 164.502(c)], making it difficult to determine if they conflict or operate in harmony. The minimum necessary principle of HIPAA [45 C.F.R. section 164.502(b)] comes into discussion in several scenarios. HIPAA-covered entities may only make and request disclosures of information in a fashion that discloses only what is reasonably minimally necessary for the particular PHI transaction or use. Other laws referring to disclosure of PHI would expectedly be preempted since they are "less stringent" than HIPAA.
State Law	Pursuant to Civil Code section 56.10(a), "[n]o provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c)." Civil Code section 56.10(a),(c)(2) provides as follows: "(c) A provider of health care, or a health care service plan may disclose medical information as follows: … (2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient."

HIPAA impact on State laws

Civil Code section 56.10(c)(2) is totally preempted by HIPAA, for the following reasons:

- There is no provision in Section 56.10(c)(2) restricting the disclosure of "psychotherapy notes". Under HIPAA, a covered entity can never disclose psychotherapy notes solely for purposes of payment activities without first obtaining an authorization from the individual who is the subject of the protected health information (unless the disclosure is to a "health oversight agency" pursuant to HIPAA section 164.512(d)). (45 C.F.R. § 164.508(a)(2).)
- There is no provision in Section 56.10(c)(2) that mandates a "minimum necessary"-type requirement for the disclosures it authorizes. The "minimum necessary" rules in HIPAA require that HIPAA-covered entities may only make and request disclosures of PHI in a fashion that discloses only what is minimally necessary for the particular PHI transaction or use

HIPAA rules

Because Civil Code section 56.10(c)(2) is totally preempted by HIPAA, the scenario is governed by HIPAA privacy rules. Pursuant to HIPAA privacy rules,

"[e]xcept as otherwise permitted or required by [the HIPAA privacy rules], a covered entity may not use or disclose protected health information without an authorization . . . ." . [45 C.F.R. § 164.506(a)]

With regard to payment activities, pursuant to HIPAA, "a covered entity may use or disclose protected health information for . . . payment . . . provided that such use or disclosure is consistent with other applicable [HIPAA privacy regulations]." (45 C.F.R. § 164.506(a).) More specifically, HIPAA provides that:

- A covered entity may obtain *consent* of the individual to use or disclose protected health information to carry out payment activities—but such consent cannot be effective to permit a use or disclosure of protected health information when a HIPAA authorization is required or when another condition must be met under HIPAA for such use or disclosure to be permissible. [45 C.F.R. § 164.506(b)]
- A covered entity may use or disclose protected health information for its own payment activities. [45 C.F.R. § 164.506(c)(1)]
- A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information [45 C.F.R. § 164.506(c)(3)]

However, under HIPAA, a covered entity can never disclose psychotherapy notes solely for purposes of payment activities without first obtaining an authorization from the individual who is the subject of the protected health information (unless the disclosure is to a "health oversight agency" pursuant to HIPAA section 164.512(d)). (45 C.F.R. § 164.508(a)(2).) Thus, a covered entity would find it impossible to comply with both this scenario and federal requirements in circumstances where the disclosure of psychotherapy notes for purposes of payment activities is contemplated. (45 C.F.R. § 160.202 (definition of "contrary").)

In addition, The HIPAA Privacy Rule requires covered entities to make reasonable efforts to limit the use, disclosure, and requests for PHI to the "minimum necessary to accomplish the intended purpose". [45 C.F.R. § 164.502(b)(1)]

Citations:

45 C.F.R. § 164.508(a)(2): Uses and disclosures for which an authorization is

HIPAA	***required.***
	(a) *Standard: Authorizations for uses and disclosures*
	(2) *Authorization required: Psychotherapy notes.*
	Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:
	(i) To carry out the following treatment, payment, or health care operations:
	(A) Use by the originator of the psychotherapy notes for treatment;
	(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision
	to practice or improve their skills in group, joint, family, or individual counseling; or
	(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and
	(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

Scenario 6	Regional Health Scenario Organization (RHIO)
	The RHIO in your region wants to access patient identifiable data from all participating organizations (and their patients) to monitor the incidence and management of diabetic patients. The RHIO also intends to monitor participating providers to rank them for the provision of preventive services to their diabetic patients.
	No reference to RHIOs was found to in State law.

Scenario 7	**Research Data Usage, ADHD (No active HIE component)** A drug manufacturer is conducting a double blind study on children under the age of 13 for a new drug for the treatment of ADD/ADHD. The study has been approved by the medical center's IRB that presides over research protocols at the major medical center where the researchers are located. All data being collected and all responses from the subjects are being completed electronically, on the same centralized and shared data base file. The principle investigator was asked by one of the researchers if he could extend the tracking of the patients an additional six months and/or use the raw data collected for his post doctoral fellow program.
Summary	In the scenario, no authorizations from patients are required if the IRB approval includes a waiver of authorization [45 C.F.R. section 164.512(i) and Civil Code section 56.21]. If not, an authorization is required for each child participating in the study (45 C.F.R. section 164.508). State law is preempted by HIPAA in this situation [CMIA – Civil Code section 56.10(c)(7)]. Assuming that the original IRB waiver did not include the additional 6-month research period, a new IRB approval and waiver authorization, or authorization for each child would be needed before the researcher could have access to the raw data for his postdoctoral fellow program.
State Law	Civil Code Section 56.05(i): "For purposes of this part:[…] (i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care." Civil Code Section 56.05(g): "For purposes of this part. […] (g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity." Civil Code Section 56.10(c)(7): "(c) A provider of health care, or a health care service plan may disclose medical information as follows: […] (7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of any patient or be violative of this part."

The State law provision allows for release without patient authorization to a number of identified persons and entities. HIPAA provides that a covered entity may use or disclose protected health information for research, without an authorization, only with the approval of an Institutional Review Board or Privacy Board. (45 C.F.R. § 164.512(i).)

TOTAL PREEMPTION. HIPAA Privacy Rule section 164. 512(i) [research disclosures], only.

Civil Code Section 56.102:

"(a) A pharmaceutical company may not require a patient, as a condition of receiving pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information that otherwise may not be disclosed under Section 56.10 or any other provision of law, unless the disclosure is for one of the following purposes:

(1) Enrollment of the patient in a patient assistance program or prescription drug discount program.

(2) Enrollment of the patient in a clinical research project.

(3) Prioritization of distribution to the patient of a prescription medicine in limited supply in the United States.

(4) Response to an inquiry from the patient communicated in writing, by telephone, or by electronic mail.

(b) Except as provided in subdivision (a) or Section 56.10, a pharmaceutical company may not disclose medical information provided to it without first obtaining a valid authorization from the patient."

HIPAA contains the general rule that a covered entity "may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization" (45 C.F.R. § 164.508(b)(4)), however, HIPAA contains only one exception to this rule in common with the State law provision: "A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure or protected health information for such research…." (45 C.F.R. § 164.508(b)(4)(i).) Accordingly, except in cases where a patient is to be enrolled in a clinical research project, this provision is contrary to HIPAA because a covered entity would find it impossible to comply with both this provision and federal requirements and because this provision would not stand as an obstacle to the accomplishment and execution of the full purposes and objectives of HIPAA. (45 C.F.R. § 160.202 (definition of "contrary").)

PARTIAL PREEMPTION. Civil Code section 56.102(a)(2) and HIPAA privacy rule section 164.508(b)(4)(i) [prohibition on conditioning of authorizations], in cases where a patient is to be enrolled in a clinical research project. HIPAA Privacy Rule section 164.508(b)(4) [prohibition on conditioning of authorizations] in all other cases.

Civil Code Section 56.11:

"Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a valid authorization for the release of this information.

An authorization for the release of medical information by a provider of health care,

health care service plan, pharmaceutical company, or contractor shall be valid if it:

(a) Is handwritten by the person who signs it or is in typeface no smaller than 14-point type.

(b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization.

(c) Is signed and dated by one of the following:

(1) The patient. A patient who is a minor may only sign an authorization for the release of medical information obtained by a provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(2) The legal representative of the patient, if the patient is a minor or an incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information obtained by the provider of health care, health care service plan, pharmaceutical company, or a contractor in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(3) The spouse of the patient or the person financially responsible for the patient, where the medical information is being sought for the sole purpose of processing an application for health insurance or for enrollment in a nonprofit hospital plan, a health care service plan, or an employee benefit plan, and where the patient is to be an enrolled spouse or dependent under the policy or plan.

(4) The beneficiary or personal representative of a deceased patient.

(d) States the specific uses and limitations on the types of medical information to be disclosed.

(e) States the name or functions of the provider of health care, health care service plan, pharmaceutical company, or contractor that may disclose the medical information.

(f) States the name or functions of the persons or entities authorized to receive the medical information.

(g) States the specific uses and limitations on the use of the medical information by the persons or entities authorized to receive the medical information.

(h) States a specific date after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.

(i) Advises the person signing the authorization of the right to receive a copy of the authorization."

Civil Code Section 56.101:

"Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records shall do so in a manner that preserves the confidentiality of the

	information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36."
Citations: **State**	***Civil Code 56.21:*** An authorization for an employer to disclose medical information shall be valid if it: (a) Is handwritten by the person who signs it or is a in typeface no smaller than 14-point type. (b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no purpose other than to execute the authorization. (c) Is signed and dated by one of the following: (1) The patient, except that a patient who is a minor may only sign an authorization for the disclosure of medical information obtained by a provider of health care in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60) of Division 1. (2) The legal representative of the patient, if the patient is a minor or incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information which pertains to a competent minor and which was created by a provider of health care in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60) of Division 1. (3) The beneficiary or personal representative of a deceased patient. (d) States the limitations, if any, on the types of medical information to be disclosed. (e) States the name or functions of the employer or person authorized to disclose the medical information. (f) States the names or functions of the persons or entities authorized to receive the medical information. (g) States the limitations, if any, on the use of the medical information by the persons or entities authorized to receive the medical information. (h) States a specific date after which the employer is no longer authorized to disclose the medical information. (i) Advises the person who signed the authorization of the right to receive a copy of the authorization.
HIPAA	***45 C.F.R. section 164.512(i)*** (i) *Standard: Uses and disclosures for research purposes*. (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that: (i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either: (A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10

CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(1) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(2) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(3) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of

protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

45 C.F.R. section 164.508: Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*

(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

(3) *Authorization required: Marketing.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: General requirements*

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by §164.530(j).

(c) *Implementation specifications: Core elements and requirements*.

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by §164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

Scenario 8	**Access by Law Enforcement (No active HIE component)** An injured nineteen (19) year old college student is brought to the ER following an automobile accident. It is standard to run blood alcohol and drug screens. The police officer investigating the accident arrives in the ER claiming that the patient may have caused the accident. The patient's parents arrive shortly afterward. The police officer requests a copy of the blood alcohol test results and the parents want to review the ER record and lab results to see if their child tested positive for drugs. These requests to print directly from the electronic health record are made to the ER staff. The patient is covered under their parent's health and auto insurance policy.
Summary	Under HIPAA [45 C.F.R. section 164.502(g)(2) & (3)] and California law [Health and Safety Code section 123110 (a) and Family Code section 6500], the parents of the 19-year-old college student do not have access to his medical information. Under HIPAA [45 C.F.R. section 164.512(a) & (f)], the information about the blood alcohol level may be disclosed to the law enforcement officer, if it is required under State law [Civil Code section 56.10(b)(9) or (c)(14)], or it is to alert law enforcement to the commission and nature of a crime. **45 C.F.R. section 164.502 (g) (3), 45 C.F.R. section 164.512 (f)(6) Does State law require the release of blood alcohol levels in ER situations?**
Citations: **State**	Health and Safety Code section 123110 (a) (a) Notwithstanding Section 5328 of the Welfare and Institutions Code, and except as provided in Sections 123115 and 123120, any adult patient of a health care provider, any minor patient authorized by law to consent to medical treatment, and any patient representative shall be entitled to inspect patient records upon presenting to the health care provider a written request for those records and upon payment of reasonable clerical costs incurred in locating and making the records available. However, a patient who is a minor shall be entitled to inspect patient records pertaining only to health care of a type for which the minor is lawfully authorized to consent. A health care provider shall permit this inspection during business hours within five working days after receipt of the written request. The inspection shall be conducted by the patient or patient's representative requesting the inspection, who may be accompanied by one other person of his or her choosing. Family Code section 6500 A minor is an individual who is under 18 years of age. The period of minority is calculated from the first minute of the day on which the individual is born to the same minute of the corresponding day completing the period of minority. Civil Code section 56.10(b)(9) or (c)(14) (b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following: (9) When otherwise specifically required by law. (c) A provider of health care or a health care service plan may disclose medical information as follows:

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

HIPAA

45 C.F.R. section 164.502(g)(2) & (3)

(g)(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification:un-emancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is anun-emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of anun-emancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with §164.524 to, protected health information about anun-emancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with §164.524 to, protected health information about anun-emancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under §164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

45 C.F.R. section 164.512(a) & (f): Uses and disclosures for which an

***authorization or opportunity to agree or object is* not required.**

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(1) The information sought is relevant and material to a legitimate law enforcement inquiry;

(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(3) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.*

(i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does

not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

Scenario 9	**Pharmacy Benefit, Formulary Alternative** The Pharmacy Benefit Manager (PBM) has a mail order pharmacy for a hospital which is self-insured and also has a closed formulary. The PBM receives a prescription from Patient X, an employee of the hospital, for the antipsychotic medication Geodon. The PBM's preferred alternatives for antipsychotics are Risperidone (Risperdal), Quetiapine (Seroquel), and Aripiprazole (Abilify). Since Geodon is not on the preferred alternatives list, the PBM sends a request to the prescribing physician to complete a prior authorization in order to fill and pay for the Geodon prescription. The PBM is in a different state than the provider's Outpatient Clinic.
Summary	State law [Health and Safety Code section 1367.24] provides guidelines for providers obtaining authorization prior to prescribing drugs that are not on the formulary for the health plan. In this scenario, the provider would be obtaining prior authorization for payment after prescribing a non-formulary drug. Since the drug is part of the patient's treatment and the pharmacy's receipt of payment, this would be a permitted disclosure under HIPAA [45 C.F.R. section 164.512(a)] and State law (CMIA – Civil Code section 56.10(c)(1)].
State Law	**Definition of Pharmacy benefit manager:** A company under contract with managed care organizations, self-insured companies, and government programs to manage pharmacy network management, drug utilization review, outcomes management, and disease management. The aim is to save money. A pharmacy benefit manager may, for example, fill drug prescriptions by mail order as part of a corporate health insurance plan. Abbreviated PBM. Pharmacy Benefits Manager, as contractors under Civil Code section 56.05. (CMIA) Health and Safety Code 1367.24 Standards under the Knox-Keene Act (a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary non-formulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a description of its process, including timelines, for responding to authorization requests for non-formulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, to its prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee. (b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a non-formulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02. (c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary non-formulary drugs shall not apply to a non-

formulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.

(d) The process described in subdivision (a) by which enrollees may obtain medically necessary non-formulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.

(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:

(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

(3) Any plan arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the plan to encourage formulary compliance or otherwise manage prescription drug benefits.

(f) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the performance of the plan in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the plan as part of its report issued pursuant to Section 1380.

(g) The director shall not publicly disclose any information reviewed pursuant to this section that is determined by the director to be confidential pursuant to state law.

(h) For purposes of this section, "authorization" means approval by the health care service plan to provide payment for the prescription drug.

(i) Non-formulary prescription drugs shall include any drug for which an enrollee's co-payment or out-of-pocket costs are different than the co-payment for a formulary prescription drug, except as otherwise provided by law or regulation or in cases in which the drug has been excluded in the plan contract pursuant to Section 1342.7.

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that a health care service plan furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

Citations:

State

Civil Code section 56.05:

For purposes of this part:

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

"Marketing" does not include any of the following:

(1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(2) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(3) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(A) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(B) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(C) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual

who has opted out after 30 calendar days from the date the individual makes the opt out request.

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs.

"Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

Civil Code section 56.10(c)(1)

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient.

This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

HIPAA

45 C.F.R. section 164.512(a)]: Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

Scenario 10	**Pharmacy Benefit, Switching BPMs** A Pharmacy Benefit Manager 1 (PBM1) has an agreement with Company A to review the companies' employees' prescription drug use and the associated costs of the drugs prescribed. The objective would be to see if the PBM1 could save the company money on their prescription drug benefit. Company A is self-insured and as part of their current benefits package, they have the prescription drug claims submitted through their current PBM (PBM2). PBM1 has requested that Company A send their electronic claims to them to complete the review.
Summary	Under HIPAA [45 C.F.R. section 164.504(f)], group health plans and health insurance issuers are permitted to disclose summary health information to the plan sponsor in certain circumstances for the purpose of obtaining premium bids. Because these disclosures fall within the definition of health care operations [45 C.F.R. section 164.501], they do not require authorization. Under State law [CMIA – Civil Code section 56.10(c)(4) & (5)]), information may be disclosed as health care operations.
Citations **State**	***Civil Code section 56.10(c)(4) & (5)*** (c) A provider of health care or a health care service plan may disclose medical information as follows: …(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges. (5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.
HIPAA	***45 C.F.R. section 164.504(f): Uses and disclosures: Organizational requirements.*** (f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under §164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart. (ii) The group health plan, or a health insurance issuer or HMO with respect to the group

health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has dis-ennrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph

(3) *Implementation specifications: Uses and Disclosures.* A group health plan may: (i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by §164.520(b)(1)(iii)(C) is included in the appropriate notice; and

(iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

45 C.F.R. section 164.501: Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons held in lawful custody* includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a

covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term *record* means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of §164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered

entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of §164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual. *Inmate* means a person incarcerated in or otherwise confined to a correctional institution.

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Payment means:

(1) The activities undertaken by

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including pre-certification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or

management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Scenario 11	**Healthcare Operations and Marketing, New Rehab Center** ABC Health Care is an integrated health delivery system comprised of ten critical access hospitals and one large tertiary hospital, DEF Medical Center, which has served as the system's primary referral center. Recently, DEF Medical Center has expanded its rehab services and created a state-of-the-art, stand-alone rehab center. Six months into operation, ABC Health Care does not feel that the rehab center is being fully utilized and is questioning the lack of rehab referrals from the critical access hospitals. ABC Health Care has requested that its critical access hospitals submit monthly reports containing patient identifiable data to the system six-sigma team to analyze patient encounters and trends for the following rehab diagnoses/procedures: ▪ Cerebrovascular Accident (CVA) ▪ Hip Fracture ▪ Total Joint Replacement Additionally, ABC Health Care is requesting that this same information, along with individual patient demographic information, be provided to the system Marketing Department. The Marketing Department plans to distribute to these individuals a brochure highlighting the new rehab center and the enhanced services available.
Summary	This scenario illustrates another aspect of the coverage problem. Even within a covered entity, discrete programs or parts of a business may or may not be subject to HIPAA [45 C.F.R. section 164.504 & 45 C.F.R. section 164.103 (definition of hybrid entity)] , based upon the how the managing entity for the program/business characterizes itself. Once the relationships are established, it needs to be determined how the HIPAA rules impact the two types of organizations. Given that there are two types of entities conducting more than one activity, individual analysis must be conducted for these two issues — i.e. providing information to the six-sigma team, and providing information to the Marketing Department [45 C.F.R. sections 164.501 (definition of marketing) & 164.502)].
	Analysis Prepared by Terri D. Keville of Manatt, Phelps & Phillips, LLP
Six-Sigma Team: **State Law**	Six Sigma is a data-driven approach to eliminating defects in processes. *See* http://www.isixsigma.com/sixsigma/six_sigma.asp?action=print In other words, in the healthcare context, Six Sigma is a quality-improvement tool. Medicare and JCAHO require hospitals to engage in quality-improvement activities (the Medicare regulation setting forth the quality assessment and performance improvement requirement for participating hospitals is 42 Code of Federal Regulations ("CFR") § 482.21; the relevant JCAHO standards include PI (Performance Improvement Standards 1.10, 2.10, 2.20, and 3.10; also relevant to this scenario are JCAHO Standards PC (Provision of Care, Treatment, and Services) 15.10, 15.20, and 15.30, relating to assessing and arranging for patients' post-discharge care needs). California medical privacy law, specifically the Confidentiality of Medical Information Act (the "CMIA," California Civil Code Section 56 *et seq*.), which governs disclosures and some uses of medical information by healthcare providers) does nothing to prohibit the use of patient information within a healthcare provider organization for quality improvement purposes, without patient authorization. The scenario does not provide any specific information about the corporate structure of ABC. However, assuming that ABC's governing body is ultimately responsible for what goes on at DEF Medical Center

	and the critical access hospitals, sharing the patient information described in the scenario with the system's six-sigma team either is not a "disclosure" (because it is an exchange of information within the same healthcare provider organization, or it is permitted as a use that is not restricted by the CMIA (as is marketing; *see* below), or it is permitted under California Civil Code Section 56.10(c)(4), which allows for disclosure of medical information without patient authorization for quality-of-care review, as follows: > The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, . . . or persons or organizations . . . responsible for . . . professional liability that a provider may incur, if the committees, agents, . . . organizations, reviewers, contractors, or persons are engaged in . . . reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges. The system and the hospitals have a legitimate, important interest in ensuring that the hospitals' stroke, hip fracture, and joint replacement patients receive necessary follow-up care, which includes rehabilitation such as physical therapy to regain lost motor function, etc. There appears to be no state-law impediment to providing the requested data to the six-sigma team for quality review – without having to obtain written patient authorization – in order for the system to determine whether these patients have been receiving appropriate referrals and follow-up care, and to consider how to address this situation if they have not.
HIPAA rules	HIPAA generally preempts all conflicting state laws unless they are more stringent, *i.e.*, more protective of patient privacy. 45 CFR § 160.203. HIPAA allows use and disclosure of protected health information ("PHI") for "health care operations" (45 CFR §§ 164.502(a)(1)(ii); 164.506(a)(1)), which expressly includes "[c]onducting quality assessment and improvement activities." 45 CFR § 164.501. Thus, analyzing whether certain kinds of patients are receiving appropriate referrals for follow-up care should qualify as the permitted use of health care operations. Since both the CMIA and HIPAA allow the six-sigma team to use this information, there is no conflict on this issue. However, HIPAA includes some restrictions not found in California law, such as a requirement that any use or disclosure of PHI include only the "minimum necessary" amount of information. 45 CFR § 164.502(b). Because this HIPAA provision applies to "use" of PHI as well as disclosure, it would apply to use of the stroke, hip fracture, and total joint replacement patients' information by the six-sigma team, even if providing that information to the team does not constitute a "disclosure." If the six-sigma team is just performing a statistical analysis of which patients in these three categories were referred for rehab, then the team members probably would not need patient names or details about patient history, other treatment, etc. If the six-sigma team is doing more than that, then ABC would need to undertake an analysis of the minimum information necessary for the team to perform its quality-improvement function.
Marketing Department: **State Law**	Under the CMIA, specifically Civil Code Section 56.10(d), a healthcare provider may not "intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient" in the absence of an express authorization from the patient. "Marketing" is defined in CMIA Section 56.05(f) as "to make a communication about a product or service that encourages recipients of the communication to purchase or use

the product or service." However, Section 56.05(f) also defines what is ***not*** "marketing." In particular, "marketing" does not include "[c]ommunications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication."

Because ABC is not receiving any remuneration from a third party, its communication of information (in the form of a brochure) about the rehab program to stroke, hip fracture, and total joint replacement patients would not be prohibited "marketing" under the CMIA.

The question then remains whether sending the brochure would be an impermissible use of "medical information" that is "not necessary to provide health care services to the patient." First, California law does not consider names and addresses alone to be "medical information." Rather, "medical information" includes information "regarding a patient's medical history, mental or physical condition, or treatment." Names and addresses may make medical information individually identifiable, but they are not medical information themselves. *See also* Civil Code Section 56.16, which permits release of such non-medical information upon request at the discretion of the provider. (This state law provision is preempted by HIPAA, which has a broader definition of protected information.) The Marketing Department could send out the brochures with only a list of names and addresses, in which event the CMIA would not be implicated. Second, since stroke, hip fracture, and total joint replacement patients require follow-up rehab care, the communication arguably is necessary and therefore permissible under state law, even if the Marketing Department receives some medical information about the patients, *e.g.*, their diagnoses, in order to determine who should get the brochures.

HIPAA rules

HIPAA also defines and restricts "marketing." As defined in 45 CFR § 164.501, "marketing" means (in relevant part):

> (1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:
>
> (i) To describe a health-related product or service (or payment for such product or service) that is provided by . . . the covered entity making the communication . . . .
>
> (ii) For treatment of the individual; or
>
> (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

Because HIPAA excludes from its definition of "marketing" communications that describe a provider's own services, as well as communications about treatment, care coordination, and alternative settings for treatment, the proposed communication (*i.e.*, sending the brochure about the DEF rehab center) to stroke, hip fracture, and total joint replacement patients in the scenario should not be considered "marketing" under HIPAA. The federal Office of Civil Rights, which is charged with enforcing HIPAA, has confirmed this in its online guidance, available at www.hhs.gov/ocr/hipaa ("The exception to the marketing definition permits communications by a covered entity about its own products or services"). Therefore, the HIPAA restrictions on marketing (*see* 45 CFR § 164.508) should not apply to the communication in the scenario, and it should be permissible without patient authorization (since it also is permissible under California law).

However, the "minimum necessary" requirement mentioned above would still apply to the

	use of PHI by the Marketing Department, which clearly does not need all of the same information that might be necessary to the six-sigma team. As noted above, the Marketing Department probably does not need and should not be given any more information than a list of patient names and addresses to whom the rehab center brochures should be sent, without any information about the patients' histories, diagnoses, or treatment.
Citations **State**	***Civil Code 56.16*** Unless there is a specific written request by the patient to the contrary, nothing in this part shall be construed to prevent a provider, upon an inquiry concerning a specific patient, from releasing at its discretion any of the following information: the patient's name, address, age, and sex; a general description of the reason for treatment (whether an injury, a burn, poisoning, or some unrelated condition); the general nature of the injury, burn, poisoning, or other condition; the general condition of the patient; and any information that is not medical information as defined in subdivision (c) of Section 56.05.
HIPAA	***42 CFR section 482.21: Condition of participation: Quality assessment and performance improvement program.*** The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. (a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors. (2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations. (b) Standard: Program data. (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization. (2) The hospital must use the data collected to-- (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement and changes that will lead to improvement. (3) The frequency and detail of data collection must be specified by the hospital's governing body. (c) Standard: Program activities. (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (2) Performance improvement activities must track medical errors and adverse patient

events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) Standard: Performance improvement projects. As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) Standard: Executive responsibilities. The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

***45 CFR section 160.203: General rule and exceptions*.**

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under §160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

45 C.F.R. section 164.103: Definitions.

As used in this part, the following terms have the following meanings:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with §164.105(a)(2)(iii)(C).

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph §164.105(a)(2)(iii)(C). *Plan sponsor* is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

45 C.F.R. section 164.502: Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with §164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §164.502(b), §164.514(d), and §164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under §164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and

(vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by §164.524 or §164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary*

(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under §164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by §164.512(a); and

(vi) Uses or disclosures that required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*

(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate

for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and (b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.*

(i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of §164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and §164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must

treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: un-emancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an un-emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an un-emancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with §164.524 to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with §164.524 to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under §164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of §164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by §164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by §164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in §164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims*

(1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime*. A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in §164.512(f)(2)(i).

45 CFR section 164.504: Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions

performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at §164.514(b)(2)(i) has been deleted, except that the geographic information described in §164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)–(d) [Removed and Reserved]

(e)(1) *Standard: Business associate contracts.*

(i) The contract or other arrangement between the covered entity and the business associate required by §164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in §164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contract.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to

the business associate with respect to such information;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section. (ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in §160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.*

(i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(1) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(1) *Standard: Requirements for group health plans.*

(i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under §164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has dis-ennrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is

inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and Disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by §164.520(b)(1)(iii)(C) is included in the appropriate notice; and

(iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.*

(1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

45 CFR section 164.506(a)(1): Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.*

Except with respect to uses or disclosures that require an authorization under §164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

45 CFR section 164.508: Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*

(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

(3) *Authorization required: Marketing.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: General requirements*

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating

determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by §164.530(j).

(c) *Implementation specifications: Core elements and requirements*.

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by §164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for

benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

Scenario 12	**Healthcare Operations and Marketing, Newborn Marketing** ABC hospital has approximately 3,600 births/year. The hospital Marketing Department is requesting identifiable data on all deliveries including mother's demographic information and birth outcome (to ensure that contact is made only with those deliveries resulting in health live births). The Marketing Department has explained that they will use the PHI for the following purposes: 1. To provide information on the hospital's new pediatric wing/services. 2. To solicit registration for the hospital's parenting classes. 3. To request donations for construction of the proposed neonatal intensive care unit They will sell the data to a local diaper company to use in marketing diaper services directly to parents.
Summary	Disclosures to provide information on the hospital's new pediatric wing/services and to solicit registration for the hospital parenting classes are allowable under State law [(CMIA - Civil Code section 56.05(f)] and HIPAA (45 C.F.R. section 164.508). HIPAA does not allow the disclosure of medical information to the marketing section listed in the scenario [45 C.F.R. sections 164.501 (definition of marketing) & 164.502)]. Disclosures to solicit donations are not restricted by the CMIA [Civil Code section 56.10(c)(4)& (5)]; however, are considered fundraising under HIPAA (45 C.F.R. section 164.514(f)]. To be disclosed as a fundraising activity, fundraising must be listed as a possible disclosure under the hospital notice of privacy practices providing the patient the opportunity to opt out of any future fundraising communications. Disclosures to sell data to a diaper service company are not permitted under State law [Civil Code section 56.05(f)], nor under HIPAA [45 C.F.R. sections 164.501 (definition of marketing) & 164.502)].
	Analysis Prepared by Terri D. Keville of Manatt, Phelps & Phillips, LLP
Providing Information About Hospital Facilities and Programs:	Under California's Confidentiality of Medical Information Act (the "CMIA," Civil Code § 56 *et seq*.), specifically Civil Code Section 56.10(d), a healthcare provider may not "intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient" in the absence of an express authorization from the patient.
State Law	"Marketing" is defined in CMIA Section 56.05(f) as "to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service." However, Section 56.05(f) also defines what is ***not*** "marketing." In particular, "marketing" does not include "[c]ommunications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication." Because ABC is not receiving any remuneration from a third party for providing information about the hospital's new pediatric wing/services, or for soliciting registration for the hospital's parenting classes (unless those classes are being presented by an outside vendor who paid ABC to solicit the registrations, which is not indicated by the scenario), ABC's communications for those purposes should not be considered

prohibited "marketing" under the CMIA.

The question then remains whether making such communications would be an impermissible use of "medical information" that is "not necessary to provide health care services to the patient." However, California law does not consider names and addresses alone to be "medical information." Rather, "medical information" includes information "regarding a patient's medical history, mental or physical condition, or treatment." Names and addresses may make medical information individually identifiable, but they are not medical information themselves. *See also* Civil Code Section 56.16, which permits release of such non-medical information upon request at the discretion of the provider. (These state law provisions are preempted by HIPAA, which has a broader definition of protected information.) The Marketing Department could send out information about pediatric-related facilities and programs such as parenting classes using only a list of names and addresses, in which event the CMIA arguably would not be implicated – as the nature of the information being received by the Marketing Department would indicate only that the women listed are mothers of children who were healthy at birth.

HIPAA rule

HIPAA generally preempts all conflicting state laws unless they are more stringent, *i.e.*, more protective of patient privacy. 45 CFR § 160.203. HIPAA allows use and disclosure of protected health information ("PHI") for "health care operations" (45 CFR §§ 164.502(a)(1)(ii); 164.506(a)(1)), but HIPAA includes some restrictions not found in California law, such as a requirement that any use or disclosure of PHI include only the "minimum necessary" amount of information. 45 CFR § 164.502(b).

HIPAA also defines and restricts "marketing." As defined in 45 CFR § 164.501, "marketing" means (in relevant part):

> (1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:
>
> (i) To describe a health-related product or service (or payment for such product or service) that is provided by . . . the covered entity making the communication . . . .
>
> (ii) For treatment of the individual; or
>
> (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

Because HIPAA excludes from its definition of "marketing" communications that describe a provider's own services, as well as communications about treatment, care coordination, and alternative settings for treatment, the proposed communications about ABC's pediatric facilities and programs in the scenario should not be considered "marketing" under HIPAA. The federal Office of Civil Rights ("OCR"), which is charged with enforcing HIPAA, has confirmed this in its online guidance, available at www.hhs.gov/ocr/hipaa ("The exception to the marketing definition permits communications by a covered entity about its own products or services"). Therefore, the HIPAA restrictions on marketing (*see* 45 CFR § 164.508) should not apply to the communications in the scenario about ABC's pediatric wing and services, or about its parenting classes, and those communications should be permissible without patient authorization (since they also are permissible without authorization under the CMIA).

However, the "minimum necessary" requirement mentioned above still would apply to the

	use of PHI by the Marketing Department. As noted above, the Marketing Department probably does not need and should not be given any more information than a list of names and addresses to whom pediatric-related information may be sent, without any other information about the former maternity patients.
***Solicitation of Donations*:** **State Law**	As explained above, the names and addresses of former ABC maternity patients are not "medical information" under the CMIA. Also, soliciting donations for construction of a neonatal intensive care unit is not attempting to influence former patients to "purchase or use" any ABC "product or service," and ABC would not be receiving any remuneration for these communications – so they would not appear to constitute marketing as defined by the CMIA. Therefore, it does not appear that the CMIA would restrict ABC's ability to send mailings (or make other communications such as telephone calls) to former maternity patients for the purpose of seeking donations to the neonatal intensive care unit construction project. Once again, however, the Marketing Department should not receive anything other than a list of names and addresses/phone numbers to be used for a specific mailing or telephone solicitation campaign.
HIPAA rule	HIPAA allows disclosure of PHI for purposes of "health care operations," and that term is expressly defined to include fundraising. 45 C.F.R. § 164.501. However, use of PHI for fundraising is limited by the requirements set forth in 45 C.F.R. § 164.514(f), which include mandates that the possibility of such use be mentioned in the hospital's notice of privacy practices, and that recipients of initial fundraising requests be informed of their right (and the means) to opt out of receiving further fundraising solicitations. That regulation provides as follows: (f)(1) Standard: Uses and disclosures for fundraising. A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without authorization meeting the requirements of 164.508: (i) Demographic information relating to an individual; and (ii) Dates of health care provided to an individual. (2) Implementation specifications: Fundraising requirements. (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(B) is included in the covered entity's notice [of privacy practices]; (ii) The covered entity must include in any fundraising materials it sends to an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications. (iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.
Sale of Patient Data to a Diaper Service	As explained above, disclosing patient medical information in exchange for remuneration from a third party definitely is "marketing" as defined by California law – and it is prohibited without patient authorization on that basis – but names and addresses are not "medical information" under California law. As discussed below, HIPAA is more stringent

Company:	and would control this proposed use of patient information.
State Law	
HIPAA rule	The OCR has stated unequivocally that "***covered entities may not sell lists of patients . . . to third parties without obtaining authorization from each person on the list.***" OCR, "Marketing," December 3, 2002, revised April 3, 2003, at p. 2 (emphasis added). Therefore, since HIPAA is more stringent than the CMIA on this subject and prohibits the Marketing Department from selling a list of ABC's maternity patients without individual patient authorizations, ABC must obtain such an authorization from each person whose name would be sold before providing any such information to the Marketing Department. The elements of a HIPAA-compliant authorization are contained in 45 C.F.R. § 164.508(a)(3)(ii), (c)(1), and (c)(2), and in an instance like this where ABC will be receiving remuneration, the authorization form must disclose that specifically. 45 C.F.R. § 164.508(a)(3). Since authorization is required, it would appear that ABC may use maternity patients' names and addresses to send them authorization forms for this purpose. However, it seems unlikely that this type of marketing effort would be justified by the number of former patients who would return signed authorizations allowing ABC to sell their names and addresses to a diaper service. HIPAA does include an exception to the authorization requirement for "face-to-face communications with an individual" (45 C.F.R. § 164.508(a)(3)(i)(A)). Therefore, it would appear to be permissible for a hospital representative to approach new mothers while they are still in the hospital, and simply ask them verbally at that time whether the hospital can provide their contact information to a diaper service. A mother who said yes could be asked to sign a written authorization (since OCR has indicated this is required, and it is not clear OCR would be satisfied with verbal authorizations obtained face-to-face). The hospital could not provide the diaper service with the name of any mother who said no, and the hospital would be obliged to require the diaper service (by contract) not to make any further use or disclosure of the information about patients who authorized disclosure of their names and contact information for this limited purpose. 45 C.F.R. §§ 164.502(e)(1)(i); 164.504(e)(2)(ii).
Citations: **State**	***Civil Code 56.10(c)(4)& (5)*** (c) A provider of health care or a health care service plan may disclose medical information as follows: (4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges. (5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly

permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

Civil Code Section 56.16

Unless there is a specific written request by the patient to the contrary, nothing in this part shall be construed to prevent a provider, upon an inquiry concerning a specific patient, from releasing at its discretion any of the following information: the patient's name, address, age, and sex; a general description of the reason for treatment (whether an injury, a burn, poisoning, or some unrelated condition); the general nature of the injury, burn, poisoning, or other condition; the general condition of the patient; and any information that is not medical information as defined in subdivision (c) of Section 56.05.

HIPAA

***45 CFR § 160.203: General rule and exceptions*.**

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under §160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

45 C.F.R. section 164.502: Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose

protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with §164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §164.502(b), §164.514(d), and §164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under §164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and

(vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by §164.524 or §164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary*

(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under §164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by §164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*

(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and

(b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.*

(i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of §164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and §164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: un-emancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of

an individual who is an un-emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of anun-emancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with §164.524 to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with §164.524 to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under §164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of §164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by §164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by §164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in §164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims*

(1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime*. A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in §164.512(f)(2)(i).

45 CFR 164.506(a)(1): Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under §164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

45 C.F.R. section 164.508: Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*

(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

(3) *Authorization required: Marketing.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: General requirements*

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by §164.530(j).

(c) *Implementation specifications: Core elements and requirements*.

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by §164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

Scenario 13	**Bioterrorism Event** A provider sees a person who has come into contact with anthrax, as determined through lab tests. The lab submits a report on this case to the local public health department and notifies their organizational patient safety officer. The public health department in the adjacent county has been contacted and has confirmed that it is also seeing anthrax cases, confirming that this is a bioterrorism event, and the State declares an emergency. Responsibility is shifted to a designated state authority to oversee and coordinate a response, and involves alerting law enforcement, hospitals, hazmat teams, and other partners, as well as informing the regional media to alert the public to symptoms and seek treatment if feel affected. The State also notifies the Federal Government of the event, and some federal agencies may have direct involvement in the event. All parties may need to be notified of specific identifiable demographic and medical details of each case as they arise to identify the source of the anthrax, locate and prosecute the parties responsible for distributing the anthrax, and protect the public from further infection.
Summary	No specific laws were found addressing release of health information for bioterrorism events. Stakeholders reported they generally use the rules provided for reporting of tuberculosis. See scenario 15 for information about laws relating to release of information to report tuberculosis.
State Law	Would Anthrax be considered a communicable disease? Currently, there is no specific statute that deals with Bioterrorism besides the allocation of federal funding and state funding. Therefore it may be possible for the government to deal with bioterrorism as a public health issue or possibly relating it to the communicable disease statutes. The local public health department would need to follow the CMIA and IPA provisions. Allow for disclosures through the exceptions dealing with public health. If the anthrax case is seen to be a communicable disease, Health and Safety Code Division 105, Section 120100 et seq. allows for the local public health agencies to report to the different necessary agencies.
HIPAA rule	HIPAA also allows for disclosure of medical information to the differing agencies dealing with bioterrorism based upon public health reasons. The public health use and disclosure allows for disclosure to public health authorities authorized to collect or receive such data. Most bioterrorism attacks such as anthrax would create risks for people to contract and/or spread the disease, which is what the public health authorities are trying to prevent. Therefore, the bioterrorism scenario would probably allow disclosure for public health reasons.
Citations: **State**	***Health and Safety Code 120100 et seq*** ***120100***. "Health officer," as used in the Communicable Disease Prevention and Control Act (Section 27) includes county, city, and district health officers, and city and district health boards, but does not include advisory health boards. ***120105.*** Whenever in the Communicable Disease Prevention and Control Act (Section 27), service or notice of any order or demand is provided for, it shall be sufficient to do so by registered or certified mail if a receipt therefore signed by the person to be served or notified is obtained. The receipt shall be prima facie evidence of the service or notice in

any civil or criminal action.

120110. As used in the Communicable Disease Prevention and Control Act (Section 27) a person has "active tuberculosis disease" when either one of the following occur:

(a) A smear or culture taken from any source in the person's body has tested positive for tuberculosis and the person has not completed the appropriate prescribed course of medication for active tuberculosis disease.

(b) There is radiographic, current clinical, or laboratory evidence sufficient to support a medical diagnosis of tuberculosis for which treatment is indicated.

120115. As used in the Communicable Disease Prevention and Control Act (Section 27) the following terms have the following meanings, unless the context indicates otherwise:

(a) "Infectious tuberculosis disease" means active or suspected active tuberculosis disease in an infectious state.

(b) "Tuberculosis infection" means the latent phase of tuberculosis, during which the infected person cannot spread tuberculosis to others.

(c) "Heightened risk of tuberculosis exposure" means likely exposure to persons with infectious tuberculosis disease.

(d) "The appropriate prescribed course of medication for tuberculosis disease" means that course recommended by the health officer, the most recent guidelines of the department, the most recent guidelines of the Centers for Disease Control and Prevention, or the most recent guidelines of the American Thoracic Society.

(e) "Directly observed therapy" means the appropriately prescribed course of treatment for tuberculosis disease in which the prescribed anti-tuberculosis medications are administered to the person or taken by the person under direct observation of a health care provider or a designee of the health care provider approved by the local health officer.

(f) An "examination" for tuberculosis infection or disease means conducting tests, including, but not limited to, Mantoux tuberculin skin tests, laboratory examination, and X-rays, as recommended by any of the following:

(1) The local health officer.

(2) The most recent guidelines of the state department.

(3) The most recent guidelines of the Centers for Disease Control and Prevention.

(4) The most recent guidelines of the American Thoracic Society.

(g) "State correctional institution" means a prison, institution, or other facility under the jurisdiction of the Department of Corrections or the Department of the Youth Authority.

(h) "Local detention facility" is defined in Section 6031.4 of the Penal Code.

(i) "Penal institution" means either a state correctional institution or a local detention facility.

(j) "Health facility" means a licensed health facility as defined in Sections 1250, 1250.2, and 1250.3.

(k) "Health officer" or "local health officer" includes his or her designee.

Scenario 14	**Employment Information, Return to Work** An employee (of any company) presents in the local emergency department for treatment of a chronic condition that has exacerbated, which is not work-related. The employee's condition necessitates a four-day leave from work for illness. The employer requires a "return to work" document for any illness requiring more than 2 days leave. The hospital Emergency Department has an EHR and their practice is to cut and paste patient information directly from the EHR and transmit the information via email to the Human Resources department of the patient's employer.
Summary	Health care providers are required under HIPAA [45 C.F.R. section 164.504(a)] to limit the amount of information provided to employers concerning an employee's health condition. Generally, information of this type are handled by the employee, e.g., the employee obtains the information and provides it to the employer. Provides do not often provide such information directly to employers, and when they do, it requires an employee authorization. The California State requirements [Civil Code section 56.11] for what constitutes a valid authorization are partially preempted by HIPAA and, accordingly, providers in this scenario would need to understand and comply with both state law and HIPAA to make the disclosure to the employer.
State Law	Pursuant to Civil Code section 56.10(a), "[n]o provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c)." In this scenario, none of the exceptions in subdivisions (b) or (c) of Civil Code section 56.10 are applicable. In addition, Civil Code section 56.11 provides in relevant part that: "Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a valid authorization for the release of this information." Civil Code Section 56.20(c) specifically requires that "[n]o employer shall use, disclose, or knowingly permit its employees or agents to use or disclose medical information which the employer possesses pertaining to its employees without the patient having first signed an authorization under Section 56.11 or Section 56.21 permitting such use or disclosure . . ., [except as set forth in subsequent list of exceptions—each of which is inapplicable to this scenario].": Accordingly, a patient authorization would be required in this case for this type of disclosure to and use by an employer. Civil Code section 56.20(b) provides: "No employee shall be discriminated against in terms or conditions of employment due to that employee's refusal to sign an authorization under this part. However, nothing in this section shall prohibit an employer from taking such action as is necessary in the absence of medical information due to an employee's refusal to sign an authorization under this part." Pursuant to Civil Code section 56.06.05(a), "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information."

Pursuant to Civil Code section 56.11, an authorization for the release of medical information by a provider of health care, health care service plan, pharmaceutical company, or contractor shall only be valid if it contains the requirements for a valid authorization listed in subdivisions (a) through (i).

Civil Code Section 56.20(a) mandates that:

> "Each employer who receives medical information shall establish appropriate procedures to ensure the confidentiality and protection from unauthorized use and disclosure of that information. These procedures may include, but are not limited to, instruction regarding confidentiality of employees and agents handling files containing medical information, and security systems restricting access to files containing medical information."

HIPAA rule

The State laws requiring an authorization in this case are not preempted by HIPAA--both these provisions and HIPAA may be fulfilled without any conflicts, because pursuant to HIPAA, an employer may receive PHI from a covered entity for any purpose, with the authorization of the individual.

However, the California requirements for what constitutes a valid authorization--Civil Code section 56.11—are partially preempted by HIPAA. Specifically, subdivision (c) is contrary to and not more stringent than HIPAA because it does not require that if a personal representative of the individual signs the authorization, a description of such representative's authority to act for the individual must also be provided. In contrast, HIPAA section 164.508(c)(1)(vi) contains this requirement. Subdivision (c) is also contrary and not more stringent than HIPAA. Also because HIPAA makes no provision for the execution of authorizations by the "spouse of the patient or the person financially responsible for the patient[,]" whereas this law does not.

Section 56.11 is also contrary to and not more stringent than HIPAA in that it does not require the inclusion of "statements adequate to place the individual on notice" of all of the following:

> "(i) The individual's right to revoke the authorization in writing, and either:
>
> (A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or
>
> (B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by Sec. 164.520, a reference to the covered entity's notice.
>
> (ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:
>
> (A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or
>
> (B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment,

enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this rule."

(45 C.F.R. § 164.508(c)(2).)

Accordingly, providers in this scenario would need to follow Civil Code section 56.11 except subdivision (c) and HIPAA Privacy Rule section 164.508.

Citations:

HIPAA

45 C.F.R. section 164.504(a): Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section: *Plan administration functions* means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor. *Summary health information* means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at §164.514(b)(2)(i) has been deleted, except that the geographic information described in §164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

45 CFR section 164.508(c)(1)(vi): Uses and disclosures for which an authorization is required.

(c) *Implementation specifications: Core elements and requirements*.

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

Scenario 15	**Public Health, TB Carrier (Active carrier, communicable disease notification)** A patient with active TB, still under treatment, has decided to move to a desert community that focuses on spiritual healing, without informing his physician. The TB is classified MDR (multi-drug resistant). The patient purchases a bus ticket - the bus ride will take a total of nine hours with two rest stops across several states. State A is made aware of the patient's intent two hours after the bus with the patient leaves. State A now needs to contact the bus company and other states with the relevant information.
Summary	Disclosure of health information during tuberculosis is permitted under State law (CMIA, Civil Code section 56.10 (b)(9) and (c)(14), if it is required or permitted by law. Disclosure of the information is clearly required by law {Health and Safety Code section 121350), but California State regulations (17 Ca. Code Regs. Section 2501(f)(4)) restrict information to be disclosed regarding substance abuse. In addition, should such disclosure be made, a health officer must notify the individual supplying their information is mandatory, has been made under law, and non-personal information may be further disclosed to understand disease patterns, develop prevention/control programs, etc. Such disclosures are permitted under HIPAA [45 C.F.R. section 164.512(b)(1)(i) and (b)(2)].
	Analysis Prepared by Terri D. Keville of Manatt, Phelps & Phillips, LLP
State Law	*Laws Governing Disclosure of Personal Information Generally* Assuming State A is California, the state's use and disclosure of personal medical information such as the patient's active TB status is governed by various laws including the California Constitution – which contains an express right to privacy in Article 1, Section 1; the Confidentiality of Medical Information Act (the CMIA, Cal. Civ. Code § 56 *et seq*.); the Information Practices Act of 1977 (the IPA, Cal. Civ. Code § 1798, *et seq*.); and the Public Records Act (the PRA, Cal. Gov't Code § 6250, *et seq*.). **1. The CMIA** The CMIA applies to providers of health care, health care service plans, and specified contractors, and thus might not necessarily apply to the state in its capacity as an overseer of public health. Nevertheless, the California Department of Health Services (DHS) has indicated in guidelines for public health officers (published jointly with several other agencies[3]) that "[m]ost, if not all, public health agencies are health care providers and are covered entities subject to HIPAA." Public Health Law Work Group, "Health Officer Practice Guide for Communicable Disease Control in California," 26 (2005). To the extent DHS considers itself a health care provider subject to HIPAA, it also would be subject to the CMIA. The CMIA contains various exceptions to the general rule that medical information may not be disclosed without patient authorization, including exceptions that would allow appropriate disclosure of a patient's status as an active TB carrier. The CMIA allows for disclosure of medical information as required by law (Civ. Code § 56.10(b)(9), and "when the disclosure is otherwise specifically authorized by law" (as opposed to required by

[3] The Public Health Law Work Group apparently includes County Counsel, City Attorneys, the California Conference of Local Health Officers, the County Health Executives Association of California, and DHS.

law) (Civ. Code § 56.10(c)(14)), which would encompass mandatory reporting of active TB. As discussed below, California's statutory scheme for TB control would require certain disclosures under these circumstances, so those disclosures would be permissible under the CMIA.

2. The IPA

The IPA acknowledges that privacy is a fundamental right protected by the California and U.S. Constitutions, and that this right is threatened by "indiscriminate" collection, maintenance, and dissemination of such information, which is increasing due to advancing technology. Therefore, the maintenance and dissemination of personal information must be "subject to strict limits." Civ. Code § 1798.1. The IPA defines "personal information" broadly to include all information that "identifies or describes an individual." Civ. Code § 1798.2(a). Under Civ. Code § 1798.24, "No agency may disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed" in accordance with one of the listed statutory exceptions.

The exception that would appear to be relevant here is found in Civ. Code § 1798.24(i). It allows disclosure by a state agency, with notice to the affected individual, as follows:

> Pursuant to a determination by the agency that maintains information that compelling circumstances exist that affect the health or safety of an individual, ***if upon disclosure notification is transmitted to the individual to whom the information pertains at his or her last known address***. Disclosure shall not be made if it is in conflict with other state or federal laws.

Thus, assuming disclosure is appropriate as discussed below with respect to the California laws relating to TB control, the disclosing agency would have to send a notice to the patient at his last known address.

3. The PRA

The PRA generally governs requests made to state agencies for public information (rather than information that the state decides to disclose on its own initiative). However, the PRA does exempt certain categories of information in the possession of government agencies from disclosure – including personal "medical files." *See* Cal. Gov't Code § 6254(c). Thus, the patient's medical information should not be subject to disclosure upon request under the PRA (but that does not mean it cannot be disclosed as appropriate in accordance with the other laws discussed in this memo).

The California Health and Human Services Agency (HSSA, of which DHS is a part) has disseminated a "Public Records Act Policy." Some of the policy statements in the HSSA's PRA Policy appear relevant to the scenario. In particular, HSSA "consider[s] all information received about an individual private unless such information is specifically identified as a public record," and "the right of privacy is a fundamental right, protected by the California Constitution and the United States Constitution and that all individuals have a reasonable expectation of privacy. Every [HSSA] employee must recognize this right and make a conscious effort to ensure the maintenance of privacy." HSSA Public Records Act Policy. This is consistent with the statutory and regulatory duties imposed by the IPA, the CMIA, and HIPAA.

b. *Laws Governing Control of Tuberculosis as an Infectious Disease*

DHS is responsible for maintaining California's program of TB control. Cal. Health & Safety Code § 121350. Within DHS there is a Division of Communicable Disease Control (DCDC), and within DCDC there is a Tuberculosis Control Brach (TCB). Other relevant entities include the California Tuberculosis Controllers Association (CTCA) and the National Tuberculosis Controllers Association (NTCA). As a practical matter, many functions relating to TB control are performed by local health officers, *i.e.*, county, city, and district health officers. *See* Health & Safety Code § 101029 (enforcement of local health officer's orders re infectious or communicable diseases); 17 Cal. Code Regs. § 2500(a)(15) (local health officers include county, city, and district health officers).

Health & Safety Code § 120175 provides that "[e]ach health officer knowing . . . that any case of the diseases made reportable by regulation of [DHS], or any other contagious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases." TB is reportable under 17 Cal. Code Regs. § 2500(b) and (j). Thus, communication of the active TB carrier's medical information would appear to be both authorized and required by law for the purpose of preventing spread of the disease and occurrence of additional cases – and consequently permitted under the CMIA, Civ. Code § 56.10(c)(14), and the IPA, Civ. Code § 1798.24(i). The communicable disease reporting regulation also provides for confidentiality except "as required by state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual." 17 Cal. Code Regs. § 2500(f).

California has a specific statutory and regulatory scheme relating to control of TB. *See* Cal. Health & Safety Code § 121350, *et seq*. Health & Safety Code § 121362 requires reporting by health care providers to the local health officer any instance in which a patient with active TB ceases treatment. California has a "Directly Observed Therapy" treatment program for tuberculosis patients who otherwise might be noncompliant, and providers of such treatment must actively attempt to locate any patient who misses an appointment. 22 Cal. Code Regs. § 51276(a)(5). California's Medi-Cal program requires participating continuing care facilities to "[r]eport to the local health department any resident who is currently taking medication for tuberculosis and plans to relocate or has relocated." 22 Cal. Code Regs. § 87861(e)(3).

Under Health & Safety Code § 121365, "[i]f the local health officer determines that the public health in general or the health of particular person is endangered by exposure to a person who is known to have active tuberculosis disease, . . . the local health officer may issue orders he or she deems necessary to protect the public health or the health of any other person, and may make application to a court for enforcement of the orders." The local health officer is authorized to order, among other things, detention, isolation, quarantine, workplace exclusion, etc. *Id*. If the patient in the scenario could be intercepted prior to leaving California, these powers could be exercised by the local public health officer in the area, and might eliminate the need to communicate with other jurisdictions.

Once a local health officer received a report of an infectious disease listed in 17 Cal. Code Regs. § 2500 (which includes TB), the local health officer must take "whatever steps deemed necessary for the investigation and control of the disease." 17 Cal. Code Regs. § 2501(a). A local health officer also must notify his or her counterpart in another jurisdiction "if there are believed to be exposed persons, living outside the jurisdiction of the health officer, who should be quarantined or evaluated for evidence of the disease."

	17 Cal. Code Regs. § 2501(b). This regulation would appear to require the local health officer in the scenario to notify local health officers along the bus route if the patient has left California. Local health officers are required to compile individual case reports on patients with TB, and to "disclose any information, including personal information, contained in an individual case report to state, federal or local public health officials in order to determine . . . the measure necessary to stop its spread." 17 Cal. Code Regs. § 2502(f)(1). This regulation also requires disclosure of the scenario patient's health information to prevent him from spreading his TB. 17 Cal. Code Regs. § 2501(f)(2) also authorizes discretionary disclosure of personal information to others "as may be necessary to prevent the spread of the disease or occurrence of additional cases." Although the subject of inter-jurisdictional travel by active TB carriers does not appear to be addressed directly in California law, DHS's website contains links to information about it. DHS has published CDHS/CTCA Joint Guidelines that include an "Inter-jurisdictional Continuity of Care Policy Statement." This document addresses situations in which a TB patient hospitalized in one jurisdiction will be discharged and plans to return to another jurisdiction. However, the recommended procedures (which include communicating with the "receiving" jurisdiction within one working day of the "sending" jurisdiction's receipt of notification of the impending discharge) also could be implemented in a situation such as the scenario. NTCA also has published recommendations on "Inter-jurisdictional Tuberculosis (TB) Notification" and created reporting forms. NTCA says notification always should be sent whenever an active TB patient will be moving for 30 days or more. People who are known to have come in close contact with the carrier should receive individual notifications. Although disclosure of the scenario patient's information clearly is required by law, the **DHS regulations impose some restrictions on disclosure of contagious disease carriers' personal information**. No information about substance abuse treatment may be disclosed as part of the patient's file without the patient's written consent. 17 Cal. Code Regs. § 2501(f)(4). Also, whenever a health officer prepares a case report, the health officer must "notify the individual from whom the information is collected that: (1) supplying personal information related to the individual's disease is mandatory; (2) the only disclosure of personal information will be pursuant to subsections 2502(f)(1) and 2502(f)(2); and (3) non-personal information may be disclosed pursuant to subsection 2502(f)(3) [to understand disease patterns, develop prevention/control programs, communicate new knowledge about the disease to the community, or conduct research]." If the scenario patient had not already received this notification (as a result of his prior identification as an active MDR TB carrier), it could be sent to his last known address and the address of his destination, if known.
HIPAA rule	HIPAA allows public health agencies to use and disclose protected health information (PHI) for public health activities, including preventing or controlling disease; reporting disease; and conducting public health surveillance, investigations, and interventions. 45 Code of Federal Regulations (CFR) § 164.512(b)(1)(i) and (b)(2). HIPAA also specifically permits public health authorities to disclose PHI to persons who may be at risk for contracting or spreading disease. 45 C.F.R. § 164.512(b)(iv). The HIPAA "minimum necessary" standard (45 C.F.R. § 164.502(b)(1)) does ***not*** apply to uses or disclosures of PHI that are *required* by law. 45 C.F.R. § 164.502(b)(2)(v). To

the extent any disclosures occurring in connection with the scenario were only authorized, rather than required by law, the minimum necessary requirement would apply to release of information regarding the patient's active TB. Even under that standard, however, it would appear to be permissible and appropriate for the state to communication all relevant information (*see* the NTCA Inter-jurisdictional Tuberculosis Notification form) in its possession about the patient's condition and treatment history to the relevant agency in the jurisdiction that is the patient's destination. TB control personnel in jurisdictions through which the patient merely is passing might not need quite as much information, and the bus company would appear to need only limited information. Exposed persons who are informed of their exposure would not need to know the patient's identity or any other specific information about the patient.

As noted above, DHS regulations place some limits on disclosure of information about infectious disease carriers (17 Cal. Code Regs. § 2502(f),(g)), and to the extent those restrictions are more stringent than HIPAA (*e.g.*, with respect to substance abuse treatment information), they would not be preempted and state officials would have to comply with them.

Citations:

State

Civil Code section 56.10 (b)(9) and (c)(14):

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

Civil Code § 1798.1:

The Legislature declares that the right to privacy is a personal and fundamental right protected by Section 1 of Article I of the Constitution of California and by the United States Constitution and that all individuals have a right of privacy in information pertaining to them. The Legislature further makes the following findings:

(a) The right to privacy is being threatened by the indiscriminate collection, maintenance, and dissemination of personal information and the lack of effective laws and legal remedies.

(b) The increasing use of computers and other sophisticated information technology has greatly magnified the potential risk to individual privacy that can occur from the maintenance of personal information.

(c) In order to protect the privacy of individuals, it is necessary that the maintenance and dissemination of personal information be subject to strict limits.

Civil Code § 1798.24(i):

No agency may disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed, as follows:

(i) Pursuant to a determination by the agency that maintains information that

compelling circumstances exist that affect the health or safety of an individual, if upon the disclosure notification is transmitted to the individual to whom the information pertains at his or her last known address. Disclosure shall not be made if it is in conflict with other state or federal laws.

Government Code § 6254(c):

Except as provided in Sections 6254.7 and 6254.13, nothing in this chapter shall be construed to require disclosure of records that are any of the following:

(c) Personnel, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.

Health & Safety Code § 101029:

The sheriff of each county, or city and county, may enforce within the county, or the city and county, all orders of the local health officer issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. Every peace officer of every political subdivision of the county, or city and county, may enforce within the area subject to his or her jurisdiction all orders of the local health officer issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. This section is not a limitation on the authority of peace officers or public officers to enforce orders of the local health officer. When deciding whether to request this assistance in enforcement of its orders, the local health officer may consider whether it would be necessary to advise the enforcement agency of any measures that should be taken to prevent infection of the enforcement officers.

Health and Safety Code section 121350:

The department shall maintain a program for the control of tuberculosis. The department shall administer the funds made available by the state for the care of tuberculosis patients.

17 Cal. Code Regs. § 2500(a)(15) Reporting to the Local Health Authority

(a) The following definitions shall govern the interpretation of this Subchapter.

(15) 'Health officer' and 'local health officer' as used in this subchapter includes county, city, and district health officers.

17 Cal. Code Regs. § 2500(b) and (j) Reporting to the Local Health Authority

(b) It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed in subsection (j) of this section, to report to the local health officer for the jurisdiction where the patient resides as required in subsection (h) of this section. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed in subsection (j) of this section may make such a report to the local health officer for the jurisdiction where the patient resides.

(j) Health care providers shall submit reports for the following diseases or conditions.
Acquired Immune Deficiency Syndrome (AIDS)
+ Amebiasis
+ Anisakiasis
r Anthrax
+ Babesiosis

r Botulism (Infant, Foodborne, Wound, Other)
r Brucellosis
+ Campylobacteriosis
Chancroid
Chlamydial Infections
r Cholera
r Ciguatera Fish Poisoning
Coccidioidomycosis
+ Colorado Tick Fever
+ Conjunctivitis, Acute Infectious of the Newborn, Specify Etiology
+ Cryptosporidiosis
Cysticercosis
r Dengue
r Diarrhea of the Newborn, Outbreaks
r Diphtheria
r Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
Echinococcosis (Hydatid Disease)
Ehrlichiosis
+ Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
r Escherichia coli O157:H7 Infection
+w Foodborne Disease
Giardiasis
Gonococcal Infections
+ Haemophilus influenzae, Invasive Disease
r Hantavirus Infections
r Hemolytic Uremic Syndrome
Hepatitis, Viral
+ Hepatitis A
Hepatitis B (specify acute case or chronic)
Hepatitis, C (specify acute case or chronic)
Hepatitis D (Delta)
Hepatitis, other, acute
Kawasaki Syndrome (Mucocutaneous Lymph Node Syndrome)
Legionellosis
Leprosy (Hansen Disease)
Leptospirosis
+ Listeriosis
Lyme Disease
+ Lymphocytic Choriomeningitis
+ Malaria
+ Measles (Rubeola)
+ Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
r Meningococcal Infections
Mumps
Non-Gonococcal Urethritis (Excluding Laboratory Confirmed Chlamydial Infections
r Paralytic Shellfish Poisoning
Pelvic Inflammatory Disease (PID)
+ Pertussis (Whooping Cough)
r Plague, Human or Animal

+ Poliomyelitis, Paralytic
+ Psittacosis
+ Q Fever
r Rabies, Human or Animal
+ Relapsing Fever
Reye Syndrome
Rheumatic Fever, Acute
Rocky Mountain Spotted Fever
Rubella (German Measles)
Rubella Syndrome, Congenital
+ Salmonellosis (Other than Typhoid Fever)
r Scombroid Fish Polsoning
r Severe Acute Respiratory Infection (SARS)
+ Shigellosis
r Smallpox (Variola)
+ Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)
+ Swimmer's Itch (Schistosomal Dermatitis)
+ Syphilis
Tetanus
Toxic Shock Syndrome
Toxoplasmosis
+ Trichinosis
+ Tuberculosis
r Tularemia
+ Typhoid Fever, Cases and Carriers
Typhus Fever
r Varicella (deaths only)
+ Vibrio Infections
r Viral Hemorrhagic Fevers (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
+ Water-associated Disease
+ West Nile virus infection
r Yellow Fever
+ Yersiniosis
r OCCURRENCE of ANY UNUSUAL DISEASE
r OUTBREAKS of ANY DISEASE (Including diseases not listed in Section 2500). Specify if institutional and/or open community.

(r) = to be reported immediately by telephone.
(+) = to be reported by mailing a report, telephoning, or electronically transmitting a report within one (1) working day of identification of the case or suspected case.
(No diamond or cross symbol) = to be reported within seven (7) calendar days by mail, telephone, or electronic report from the time of identification. (w) = when two (2) or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness, they should be reported immediately by telephone.

17 Cal. Code Regs. § 2502(f),(g)), Reports by Local Health Officer to State Department of Health Services

(f) Confidentiality. Information reported pursuant to this section is acquired in confidence and shall not be disclosed by the local health officer except as authorized by these regulations, as required by state or federal law, or with the written consent of the individual to whom the information pertains or to the legal representative of that individual.

(1) A health officer shall disclose any information, including personal information, contained in an individual case report to state, federal or local public health officials in order to determine the existence of a disease, its likely cause or the measures necessary to stop its spread.

(2) A health officer may for purposes of his or her investigation disclose any information contained in an individual case report, including personal information, as may be necessary to prevent the spread of disease or occurrence of additional cases.

(3) A health officer may disclose any information contained in an individual case report to any person or entity if the disclosure may occur without linking the information disclosed to the individual to whom it pertains, and the purpose of the disclosure is to increase understanding of disease patterns, to develop prevention and control programs, to communicate new knowledge about a disease to the community, or for research.

(4) Notwithstanding subsections (1), (2), and (3) above, no information that would directly or indirectly identify an individual as one who has applied for or been given services for alcohol or other drug abuse by a federally assisted drug or alcohol abuse treatment program (as defined in 42 C.F.R. s 2.11) shall be included in an individual case report or otherwise disclosed absent the individual's written consent.

(g) Whenever the health officer collects personal information in order to prepare an individual case report required by subsection (b), the health officer shall notify the individual from whom the information is collected that: (1) supplying personal information related to the individual's disease is mandatory; (2) the only disclosure of personal information will be pursuant to subsections 2502(f(1) and 2502(f)(2); and (3) non-personal information may be disclosed pursuant to subsection 2502(f)(3).

HIPAA

***45 C.F.R. § 164.502(b)(1): Uses and disclosures of protected health information: general rules*.**

(b) *Standard: Minimum necessary*

(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

45 C.F.R. § 164.502(b)(2)(v): Uses and disclosures of protected health information: general rules.

(b) *Standard: Minimum necessary*

(2) *Minimum necessary does not apply.* This requirement does not apply to: (v) Uses or disclosures that are required by law, as described by §164.512(a); and

***45 C.F.R. section 164.512(b)(1)(i) and (b)(2):* Uses and disclosures for which an**

authorization or *opportunity* to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(b) *Standard: uses and disclosures for public health activities*

(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

Scenario 16	**Public Health, Newborn Screening** A newborn's screening test comes up positive for a state-mandated screening test and the state lab test results are made available to the child's physicians and specialty care centers specializing in the disorder via an Interactive Voice Response system. The state lab also enters the information in its registry, and tracks the child over time through the child's physicians. The state public health department provides services for this disorder and notifies the physician that the child is eligible for those programs.
Summary	Information about PKU lab tests may be shared for treatment purposes under HIPAA (45 C.F.R. section 164.502(c)] and State law [CMIA, Civil Code section 56.10(c)(1)]. The use of the information for a state registry could be exchanged if required by a law [HIPAA – 45 C.F.R. section 164.512(a) and State law – CMIA, Civil Code section 56.10(b)(9)] that would require the exchange of the information between the state lab and the child's physician. A similar law would be needed to allow the exchange of the information within the state public health department to inform physicians about their program. Unless there is some kind of need to exchange health information to make the mother eligible for special food products, the purchase of this food should not require any laws. If there is a need to exchange health information, a similar law would be needed as for the state registry exchange and the state lab to child's physician exchange. There are no California law concerning security that would bar the use of Interactive Voice Response systems.
State Law	**Specific newborn screening-related laws:** • Health and Safety Code section 125000, et seq., establishes a genetic disease unit, the Genetic Disease Branch, which coordinates the programs for newborn screening. • Health and Safety Code section 124975(j) provides that the information from hereditary disorder programs such as the PKU and other genetic disorder screening through the California newborn screening program is to be held strictly confidential. • Health and Safety Code section 127660 et seq. provides for the University of California to assess services such as screening. This chapter is to be repealed January 1, 2007. • Health and Safety Code section 123975 creates a newborn hearing screening under the California Children's Services Program, but this screening is voluntary.
Citations: **State**	***Civil Code section 56.10(b)(9)*** (b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following: (9) When otherwise specifically required by law. ***Civil Code section 56.10(c)(1)*** (c) A provider of health care or a health care service plan may disclose medical information as follows: (1) The information may be disclosed to providers of health care, health care service

plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

Health and Safety Code section 123975

(a) The department, in consultation with selected representatives of participating neonatal intensive care units, shall establish a system to screen all newborns and infants for hearing loss as defined in subdivision (e) of Section 124116 and create and maintain a system of assessment and follow-up services for newborns and infants identified by the screening in approved neonatal intensive care units participating in the California Children's Services Program. Screening, assessment and follow-up services and reporting of these services shall be provided in a manner consistent with Article 6.5 (commencing with Section 124115) of Chapter 3.

This section shall not be applicable to a newborn child whose parent or guardian objects to the tests on the ground that the tests conflict with his or her religious beliefs or practices.

(b) It is the intent of the Legislature, in enacting this section, to ensure the establishment and maintenance of protocols and quality of standards.

(c) The department shall implement this section for newborns and infants in neonatal intensive care units participating in the California Children's Services Program.

Health and Safety Code section 124975(j)

The Legislature hereby finds and declares that:

(j) Participation of persons in hereditary disorders programs in the State of California should be wholly voluntary, except for initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program.

All information obtained from persons involved in hereditary disorders programs in the state should be held strictly confidential.

Health and Safety Code section 125000, et seq

125000. (a) It is the policy of the State of California to make every effort to detect, as early as possible, phenylketonuria and other preventable heritable or congenital disorders leading to mental retardation or physical defects.

The department shall establish a genetic disease unit, which shall coordinate all programs of the department in the area of genetic disease. The unit shall promote a statewide program of information, testing, and counseling services and shall have the responsibility of designating tests and regulations to be used in executing this program.

The information, tests, and counseling for children shall be in accordance with accepted medical practices and shall be administered to each child born in California once the department has established appropriate regulations and testing methods. The information, tests, and counseling for pregnant women shall be in accordance with accepted medical practices and shall be offered to each pregnant woman in California once the department has established appropriate regulations and testing methods. These regulations shall follow the standards and principles specified in Section 124980.

The department may provide laboratory testing facilities or contract with any laboratory that it deems qualified to conduct tests required under this section. However, notwithstanding Section 125005, provision of laboratory testing facilities by the department shall be contingent upon the provision of funding therefore by specific appropriation to the Genetic Disease Testing Fund enacted by the Legislature. If moneys appropriated for purposes of this section are not authorized for expenditure to provide laboratory facilities, the department may nevertheless contract to provide laboratory testing services pursuant to this section and shall perform laboratory services, including, but not limited to, quality control, confirmatory, and emergency testing, necessary to ensure the objectives of this program.

(b) The department shall charge a fee for any tests performed pursuant to this section. The amount of the fee shall be established and periodically adjusted by the director in order to meet the costs of this section.

(c) The department shall inform all hospitals or physicians and surgeons, or both, of required regulations and tests and may alter or withdraw any of these requirements whenever sound medical practice so indicates. To the extent practicable, the department shall provide notice to hospitals and other payers in advance of any increase in the fees charged for the program.

(d) This section shall not apply if a parent or guardian of the newborn child objects to a test on the ground that the test conflicts with his or her religious beliefs or practices.

(e) The genetic disease unit is authorized to make grants or contracts or payments to vendors approved by the department for all of the following:

(1) Testing and counseling services.

(2) Demonstration projects to determine the desirability and feasibility of additional tests or new genetic services.

(3) To initiate the development of genetic services in areas of need.

(4) To purchase or provide genetic services from any sums as are appropriated for this purpose.

(f) The genetic disease unit shall evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, including, but not limited to, biotinidase deficiency and cystic fibrosis. The genetic disease unit shall also evaluate and prepare recommendations on the availability and effectiveness of preventative follow-up interventions, including the use of specialized medically necessary dietary products.

It is the intent of the Legislature that funds for the support of the evaluations and recommendations required pursuant to this subdivision, and for the activities authorized pursuant to subdivision (e), shall be provided in the annual Budget Act appropriation from the Genetic Disease Testing Fund.

(g) Health care providers that contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership, may provide, without contracting with the department, any or all of the testing and counseling services required to be provided under this section or the regulations adopted pursuant thereto, if the services meet the quality standards and adhere to the regulations established by the department and the plan pays that portion of a fee established under this section that is directly attributable to the department's cost of administering the testing or counseling service and to any required testing or counseling services provided by the state for plan members. The payment by the plan, as provided in this subdivision, shall be deemed to

fulfill any obligation the provider or the provider's patient may have to the department to pay a fee in connection with the testing or counseling service.

(h) The department may appoint experts in the area of genetic screening, including, but not limited to, cytogenetics, molecular biology, prenatal, specimen collection, and ultrasound to provide expert advice and opinion on the interpretation and enforcement of regulations adopted pursuant to this section. These experts shall be designated agents of the state with respect to their assignments. These experts shall receive no salary, but shall be reimbursed for expenses associated with the purposes of this section. All expenses of the experts for the purposes of this section shall be paid from the Genetic Disease Testing Fund.

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic screening and follow-up services for persons who have the screening.

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia as soon as possible. The department shall provide information with respect to these disorders and available testing resources to all women receiving prenatal care and to all women admitted to a hospital for delivery. If the department is unable to provide this statewide screening by August 1, 2005, the department shall temporarily obtain these testing services through a competitive bid process from one or more public or private laboratories that meet the department's requirements for testing, quality assurance, and reporting. If the department determines that contracting for these services is more cost-effective, and meets the other requirements of this chapter, than purchasing the tandem mass spectrometry equipment themselves, the department shall contract with one or more public or private laboratories.

(c) The department shall report to the Legislature regarding the progress of the program on or before July 1, 2006. The report shall include the costs for screening, follow-up, and treatment as compared to costs and morbidity averted for each condition tested for in the program.

Health and Safety Code section 127660 et seq

127660. (a) The Legislature hereby requests the University of California to assess legislation proposing a mandated benefit or service, as defined in subdivision (d), and to prepare a written analysis with relevant data on the following:

(1) Public health impacts, including, but not limited to, all of the following:

(A) The impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care.

(B) The impact on the health of the community, including diseases and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature.

(C) The extent to which the proposed service reduces premature death and the economic loss associated with disease.

(2) Medical impacts, including, but not limited to, all of the following:

(A) The extent to which the benefit or service is generally recognized by the medical community as being effective in the screening, diagnosis, or treatment of a condition or disease, as demonstrated by a review of scientific and peer reviewed medical literature.

(B) The extent to which the benefit or service is generally available and utilized by treating physicians.

(C) The contribution of the benefit or service to the health status of the population, including the results of any research demonstrating the efficacy of the benefit or service compared to alternatives, including not providing the benefit or service.

(D) The extent to which the proposed services do not diminish or eliminate access to currently available health care services.

(3) Financial impacts, including, but not limited to, all of the following:

(A) The extent to which the coverage will increase or decrease the benefit or cost of the service.

(B) The extent to which the coverage will increase the utilization of the benefit or service, or will be a substitute for, or affect the cost of, alternative services.

(C) The extent to which the coverage will increase or decrease the administrative expenses of health care service plans and health insurers and the premium and expenses of subscribers, enrollees, and policyholders.

(D) The impact of this coverage on the total cost of health care.

(E) The potential cost or savings to the private sector, including the impact on small employers as defined in paragraph (1) of subdivision (l) of Section 1357, the Public Employees' Retirement System, other retirement systems funded by the state or by a local government, individuals purchasing individual health insurance, and publicly funded state health insurance programs, including the Medi-Cal program and the Healthy Families Program.

(F) The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities.

(G) The extent to which the proposed benefit or service does not diminish or eliminate access to currently available health care services.

(H) The extent to which the benefit or service is generally utilized by a significant portion of the population.

(I) The extent to which health care coverage for the benefit or service is already generally available.

(J) The level of public demand for health care coverage for the benefit or service, including the level of interest of collective bargaining agents in negotiating privately for inclusion of this coverage in group contracts, and the extent to which the mandated benefit or service is covered by self-funded employer groups.

(K) In assessing and preparing a written analysis of the financial impact of a mandated benefit pursuant to this paragraph, the Legislature requests the University of California to use a certified actuary or other person with relevant knowledge and expertise to determine the financial impact.

(b) The Legislature requests that the University of California provide every analysis to the appropriate policy and fiscal committees of the Legislature not later than 60 days after receiving a request made pursuant to Section 127661. In addition, the Legislature requests that the university post every analysis on the Internet and make every analysis

available to the public upon request.

(c) The Legislature requests that the University of California first analyze any of the following benefit mandates proposed in the 2001-02 Legislative Session, if introduced or proposed to be introduced at the start of the 2003-04 Legislative Session, and a request for an analysis is made by the author or the relevant policy committee chair:

(1) Bone marrow testing for prospective donors.

(2) Infertility treatment.

(3) Specified ovarian cancer screening and diagnostic tests.

(4) Medically necessary prescription drugs.

(5) Wigs for patients who have undergone chemotherapy.

(6) Bone mineral density testing for osteoporosis.

(7) Hearing aids.

(8) Hyperbaric oxygen therapy for an acute or chronic brain condition.

(9) Substance-related disorders.

(10) Genetic disease tests for certain populations.

(d) As used in this section, "mandated benefit or service" means a proposed statute that requires a health care service plan or a health insurer, or both, to do any of the following:

(1) Permit a person insured or covered under the policy or contract to obtain health care treatment or services from a particular type of health care provider.

(2) Offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition.

(3) Offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

127661. A request pursuant to this chapter may be made by an appropriate policy or fiscal committee chairperson, the Speaker of the Assembly, or the President pro Tempore of the Senate, who shall forward the introduced bill to the University of California for assessment.

127662. (a) In order to effectively support the University of California and its work in implementing this chapter, there is hereby established in the State Treasury, the Health Care Benefits Fund. The university's work in providing the bill analyses shall be supported from the fund.

(b) For fiscal years 2002-03 to 2005-06, inclusive, each health care service plan, except a specialized health care service plan, and each health insurer, as defined in Section 106 of the Insurance Code, shall be assessed an annual fee in an amount determined through regulation. The amount of the fee shall be determined by the Department of Managed Health Care and the Department of Insurance in consultation with the university and shall be limited to the amount necessary to fund the actual and necessary expenses of the university and its work in implementing this chapter. The total annual assessment on health care service plans and health insurers shall not exceed two million dollars ($2,000,000).

(c) The Department of Managed Health Care and the Department of Insurance, in coordination with the university, shall assess the health care service plans and health

insurers, respectively, for the costs required to fund the university's activities pursuant to subdivision (b).

(1) Health care service plans shall be notified of the assessment on or before June 15 of each year with the annual assessment notice issued pursuant to Section 1356. The assessment pursuant to this section is separate and independent of the assessments in Section 1356.

(2) Health insurers shall be noticed of the assessment in accordance with the notice for the annual assessment or quarterly premium tax revenues.

(3) The assessed fees required pursuant to subdivision (b) shall be paid on an annual basis no later than August 1 of each year. The Department of Managed Health Care and the Department of Insurance shall forward the assessed fees to the Controller for deposit in the Health Care Benefits Fund immediately following their receipt.

(4) "Health insurance," as used in this subdivision, does not include Medicare supplement, vision-only, dental-only, or CHAMPUS supplement insurance, or hospital indemnity, accident-only, or specified disease insurance that does not pay benefits on a fixed benefit, cash payment only basis.

127663. In order to avoid conflicts of interest, the Legislature requests the University of California to develop and implement conflict-of-interest provisions to prohibit a person from participating in any analysis in which the person knows or has reason to know he or she has a material financial interest, including, but not limited to, a person who has a consulting or other agreement with a person or organization that would be affected by the legislation.

127664. The Legislature requests the University of California to submit a report to the Governor and the Legislature no later than January 1, 2006, regarding the implementation of this chapter. Initial startup funding for the university shall be loaned to the Health Care Benefits Fund from the Managed Care Fund created pursuant to Section 1341.4 and the Insurance Fund created pursuant to Section 12975.8 of the Insurance Code. The Health Care Benefits Fund shall reimburse the Managed Care Fund and the Insurance Fund by September 30, 2003, from the 2003-04 fiscal year assessments received under subdivision (b) of Section 127662. The annual fee for the 2002-03 fiscal year shall be collected at the time the 2003-04 fiscal year assessments are made.

127665. This chapter shall remain in effect until January 1, 2007, and shall be repealed as of that date, unless a later enacted statute that becomes operative on or before January 1, 2007, deletes or extends that date.

HIPAA

45 C.F.R. section 164.502(c): Uses and disclosures of protected health information: general rules.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

45 C.F.R. section 164.512(a): Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*(

1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

Scenario 17	**Public Health, Homeless Shelters** A homeless man arrives at a county shelter and is found to be a drug addict and in need of medical care. The person does have a primary provider, is sent there for the medical care, and is referred to a hospital-affiliated drug treatment clinic for his addition under a county program. The addiction center must report treatment information back to the county for program reimbursement, and back to the shelter to verify that the person is in treatment. Someone claiming to be a relation of the homeless man requests information from the homeless shelter on all the health services the man has received. The staff at the homeless shelter is working to connect the homeless man with his relative.
Summary	The CMIA provides that the information agencies receive can be shared among one another for payment purposes [HIPAA – 45 C.F.R. section 164.512(c) and Civil Code section 56.10(c)(2)]. Yet State law provides that use and disclosure of medical information subject to federal and drug abuse regulations are not subject to the CMIA [Civil Code section 56.30(i)]. However, if the drug and alcohol facility is funded with federal monies, the federal drug and alcohol treatment regulations [42 C.F.R. Parts 2.1 – 2.67] may affect the sharing of the information.
	Analysis Prepared by Terri D. Keville of Manatt, Phelps & Phillips, LLP
State Law	With respect to the substance abuse treatment records at issue here, most state laws, such as the Confidentiality of Medical Information Act ("CMIA"), California Civil Code Section 56 *et seq*., likely are preempted by the federal statutes and regulations governing alcohol and drug abuse treatment. *See* Cal. Civ. Code § 56.30(i), which expressly states that disclosure and use of medical information subject to the federal alcohol and drug abuse regulations are ***not*** subject to the CMIA. As discussed below under Federal Law, the federal regulations apply to any drug or alcohol treatment program that receives any type of federal assistance, either directly or indirectly, which probably includes the hospital-based county drug treatment program in the scenario. The federal drug abuse regulations are very restrictive, and prohibit disclosure of information in at least some situations where it otherwise would be permitted by the CMIA and the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). For example, Civil Code Section 56.10(b) provides that "[a] provider of health care . . . shall disclose medical information if the disclosure is compelled by any of the following: . . . (9) When otherwise specifically required by law." The scenario states that the drug treatment clinic "must" report treatment information to the county program (which also would be permitted under Civil Code Section 56.10(c)(2) as necessary to receive payment from a governmental authority) and to the shelter. Therefore, to the extent the word "must" indicates that disclosure is required by some state law or county ordinance, those disclosures would be permitted without authorization under the CMIA, which also does not place any limitation on the scope of the information that may be disclosed. However, CMIA sections 56.10(b) and (c) do ***not*** apply if the federal laws apply, as stated in Section 56.30(i). *See also* 42 Code of Federal Regulations ("CFR") § 2.20 ("no state law may either authorize or compel any disclosure prohibited by these [federal drug and alcohol abuse] regulations"). California does have a statutory provision, Health and Safety Code Section 11845.5, which essentially tracks the federal regulations, and applies to programs conducted, regulated, or assisted by the state Department of Alcohol

and Drug Programs. Such programs must be registered with the county in which they are located. The scenario does not indicate whether the program is regulated by the state department, but the requirements would appear to be the same either way. Additional state requirements might apply if the homeless man is found to be "gravely disabled" and subject to involuntary commitment (*see* California Welfare and Institutions Code Section 5328), but that analysis is beyond the scope of this scenario.

Both HIPAA and the CMIA (to the extent any of its provisions are more stringent than the HIPAA privacy regulations) *would* govern release of medical information by the primary care provider about treatment that the homeless man received from that provider, but the scenario does not indicate that the homeless shelter has received any such information. Therefore, the shelter simply could inform the inquiring relative that it has no general medical treatment information about the homeless man.

The scenario does not indicate that the person who claims to be a relative presented the shelter with a signed consent form from the homeless man authorizing the shelter to provide any medical information about him. Unless the shelter received such a written consent that complied with all of the requirements of HIPAA and the federal substance abuse regulations (as explained below), the shelter could not tell the purported relative anything about the substance abuse treatment – including that the homeless man was referred to it – except to inform the relative what the rules are about such information.

HIPAA rule

Federal Regulations Governing Confidentiality of Drug and Alcohol Abuse Patient Records

The federal drug and alcohol treatment regulations, 42 CFR §§ 2.1 – 2.67, promulgated in accordance with 42 United States Code Sections 290dd-2(g), apply to any drug or alcohol treatment program that receives any type of federal assistance, direct or indirect. A "program" includes "[a]n individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment," and "[a]n identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment." 42 CFR § 2.11. "Federal assistance" includes Medicare certification, registration to dispense drugs under the Controlled Substances Act (to the extent used in treatment), and being "supported by funds provided by any department or agency of the United states by being . . . [c]onducted by a State or local government unit which, through general or specific revenue sharing or other forms of assistance, received Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program"). 42 CFR § 2.12(b)(2)(i), (ii), (3)(ii). Therefore, the hospital-based county drug treatment program in the scenario would appear to be covered by the federal regulations.

The federal regulations prohibit disclosure of any information about drug or alcohol treatment – including the fact that someone is participating – to *anyone*, with certain very limited exceptions. If one of the exceptions applies, then disclosure is permitted, but it is *never* compelled. 42 CFR § 2.3(b)(1). The regulations "are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse treatment program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment." 42 CFR § 2.3(b)(2).

One specific exception to the general prohibition on disclosure of information is for "[c]ommunication within a program or between a program and an entity having direct

administrative control over that program," if they are "communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for the treatment of alcohol or drug abuse . . . ." 42 CFR § 2.12(c)(3). Since the program in the scenario is a "county program," it would appear that the hospital-based clinic can communicate such information to county personnel charged with operating the county's drug abuse referral program. That is, the county and the clinic may be considered part of the same "program" (or, depending upon the management structure, the county may have "administrative oversight" over the program).[4]

Any disclosure that is permitted under the federal regulations "must be limited to that information which is necessary to carry out the purpose of the disclosure." 42 CFR § 2.13(a). Thus, it is appropriate for the clinic to communicate to the county information necessary for the clinic to obtain reimbursement. It is less clear that it is necessary for the homeless shelter to know that the homeless man is in treatment.

Assuming that the homeless shelter is considered part of the county program and is informed of the patient's participation in drug abuse treatment, the shelter would be subject to the regulation governing responses to requests for information. That regulation, 42 CFR § 2.13(c)(2), provides as follows:

> Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

Therefore, assuming the homeless shelter is considered part of the program and has been informed of the homeless man's participation in the drug program, the shelter should give the inquiring relative a copy of the federal regulations and inform the relative that the regulations restrict disclosure of all alcohol and drug abuse records. Shelter personnel should say nothing about the homeless man himself.

As noted above, the scenario does not say that the person claiming to be a relative presented the shelter with a written authorization from the homeless man for release of

[4] Even if the county and the clinic were not part of the same program, the county might be entitled to receive information as a third party payer. Although providing information to third party payers is not expressly listed as one of the exceptions to the general prohibition on disclosing any drug or alcohol treatment information, the federal regulations do acknowledge that drug and alcohol treatment programs may provide information to third party payers in order to obtain reimbursement. *See* 42 CFR § 2.11 (defining "[t]hird party payer" as "a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local government benefits"); 42 CFR § 2.12(d)(2) (stating that "the restrictions on disclosure in these regulations apply to: [¶] (i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs"). Under this analysis, however, it is not clear that there would be any authorization for the clinic to disclose information to the county homeless shelter, which probably has no part in the payment function.

his medical information, including drug abuse treatment information. However, such information can be released pursuant to a previously executed, signed consent for release of drug abuse records from the patient that fulfills all the requirements of 42 CFR § 2.31 (which includes a sample form), and specifically says that the relative can be told that the patient is in drug treatment, and any other information specifically listed on the consent form and in the possession of the shelter. 42 CFR § 2.1. As discussed below, since this would not be a disclosure authorized without patient consent under HIPAA, the consent form also would have to include some additional elements required by the HIPAA privacy regulations. If the shelter disclosed information pursuant to a written consent, it also would have to inform the relative in writing that he/she cannot further disclose the information. 42 CFR § 2.32.

HIPAA

According to the Substance Abuse and Mental Health Services Administration ("SAMHSA") of the federal Department of Health and Human Services, drug abuse programs have to comply with both the federal drug and alcohol abuse regulations discussed above and HIPAA, but generally they can comply with both simply by following the federal regulations. Specifically, SAMHSA has stated as follows:

> Substance abuse treatment programs that already are complying with Part 2 should not have a difficult time complying with the Privacy Rule, as it parallels the requirements of Part 2 in many areas. Programs subject to both sets of rules must comply with both, unless there is a conflict between them. Generally, this will mean that substance abuse treatment programs should continue to follow the Part 2 regulations. In some instances, programs will have to establish new policies and procedures or alter existing policies and practices. In the event a program identifies a conflict between the rules, it should notify the Substance Abuse and Mental Health Services Administration of HHS immediately for assistance in resolving the conflict.

SAMHSA, *The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs*, p. 3 (2004). available at http://www.hipaa.samhsa.gov/Part2ComparisonCleared.htm.

The SAMHSA comparison document notes that in situations where a disclosure based on the patient's written consent would not otherwise be authorized under the HIPAA privacy regulations, the written consent form must include some elements required by HIPAA but not by the federal drug and alcohol abuse regulations. It explains as follows:

> The core required elements for the Privacy Rule written authorization are similar to those of Part 2. However, to comply with the Privacy Rule authorization requirements, the Part 2 consent must also contain a statement reflecting the ability or inability of the substance abuse treatment program to condition treatment on whether the patient signs the form as described in 45 CFR §164.508(c)(2)(ii). In addition, the consent may be signed by a personal representative, and if so, must include a description of such representative's authority to act for the patient. See 45 CFR §164.508(c)(1)(vi). Finally, the consent must be written in plain language. See 45 CFR §164.508(c)(3).
>
> The requirements above must be met with respect to the Part 2 consent form when the purpose of the disclosure is *not* for "treatment, payment or

health care operations" or for any other permitted or required disclosure under the Privacy Rule. See 45 CFR §164.502(a). The statements would have to be added when the consent form authorizes a program to make a disclosure for which an authorization is required under the Privacy Rule, e.g., those disclosures addressed by 45 CFR §164.508.

The Privacy Rule imposes three additional steps programs must take when disclosing information pursuant to a patient's written consent:

- Programs must ensure that the consent complies with the applicable requirements of 45 CFR §164.508.
- Programs must give patients a copy of the signed form (45 CFR §164.508(c)(4)).
- Programs must keep a copy of each signed form for six (6) years from its expiration date (45 CFR §164.508(b)(6)).

Therefore, substance abuse treatment programs should generally continue to use the consent form for disclosures subject to Part 2. If the Privacy Rule requires authorization for the disclosures, the substance abuse treatment program may use the Part 2 consent form with additional elements required by the Privacy Rule as listed above.

SAMHSA, *supra*, at p. 7 (footnote omitted).

Citations

State

Civil Code section 56.10(c)(2)

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

Health and Safety Code Section 11845.5

(a) The identity and records of the identity, diagnosis, prognosis, or treatment of any patient, which identity and records are maintained in connection with the performance of any alcohol and other drug abuse treatment or prevention effort or function conducted, regulated, or directly or indirectly assisted by the department shall, except as provided in subdivision (c), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subdivision (b).

(b) The content of any records referred to in subdivision (a) may be disclosed in

accordance with the prior written consent of the client with respect to whom the record is maintained, but only to the extent, under the circumstances, and for the purposes as clearly stated in the release of information signed by the client.

(c) Whether or not the client, with respect to whom any given record referred to in subdivision (a) is maintained, gives his or her written consent, the content of the record may be disclosed as follows:

(1) In communications between qualified professional persons employed by the treatment or prevention program in the provision of service.

(2) To qualified medical persons not employed by the treatment program to the extent necessary to meet a bona fide medical emergency.

(3) To qualified personnel for the purpose of conducting scientific research, management audits, financial and compliance audits, or program evaluation, but the personnel may not identify, directly or indirectly, any individual client in any report of the research, audit, or evaluation, or otherwise disclose patient identities in any manner. For purposes of this paragraph, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of work in which they are engaged, and who, when working as part of an organization, are performing that work with adequate administrative safeguards against unauthorized disclosures.

(4) If the recipient of services is a minor, ward, or conservatee, and his or her parent, guardian, or conservator designates, in writing, persons to whom his or her identity in records or information may be disclosed, except that nothing in this section shall be construed to compel a physician and surgeon, psychologist, social worker, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of the client's family.

(5) If authorized by a court of competent jurisdiction granted after application showing probable cause therefore, as provided in subdivision (c) of Section 1524 of the Penal Code.

(d) Except as authorized by a court order granted under paragraph (5) of subdivision (c), no record referred to in subdivision (a) may be used to initiate or substantiate any criminal charges against a client or to conduct any investigation of a client.

(e) The prohibitions of this section shall continue to apply to records concerning any individual who has been a client, irrespective of whether he or she ceases to be a client.

Welfare and Institutions Code Section 5328

All information and records obtained in the course of providing services under Division 4 (commencing with Section 4000), Division 4.1 (commencing with Section 4400), Division 4.5 (commencing with Section 4500), Division 5 (commencing with Section 5000), Division 6 (commencing with Section 6000), or Division 7 (commencing with Section 7100), to either voluntary or involuntary recipients of services shall be confidential. Information and records obtained in the course of providing similar services to either voluntary or involuntary recipients prior to 1969 shall also be confidential. Information and records shall be disclosed only in any of the following cases:

(a) In communications between qualified professional persons in the provision of services or appropriate referrals, or in the course of conservatorship proceedings. The consent of the patient, or his or her guardian or conservator shall be obtained before information or records may be disclosed by a professional person employed by a facility to a professional person not employed by the facility who does not have the medical or

psychological responsibility for the patient's care.

(b) When the patient, with the approval of the physician, licensed psychologist, social worker with a master's degree in social work, or licensed marriage and family therapist, who is in charge of the patient, designates persons to whom information or records may be released, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family. Nothing in this subdivision shall be construed to authorize a licensed marriage and family therapist to provide services or to be in charge of a patient's care beyond his or her lawful scope of practice.

(c) To the extent necessary for a recipient to make a claim, or for a claim to be made on behalf of a recipient for aid, insurance, or medical assistance to which he or she may be entitled.

(d) If the recipient of services is a minor, ward, or conservatee, and his or her parent, guardian, guardian ad litem, or conservator designates, in writing, persons to whom records or information may be disclosed, except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(e) For research, provided that the Director of Mental Health or the Director of Developmental Services designates by regulation, rules for the conduct of research and requires the research to be first reviewed by the appropriate institutional review board or boards. The rules shall include, but need not be limited to, the requirement that all researchers shall sign an oath of confidentiality as follows:

Date _____

As a condition of doing research concerning persons who have received services from ____ (fill in the facility, agency or person), I, ____, agree to obtain the prior informed consent of such persons who have received services to the maximum degree possible as determined by the appropriate institutional review board or boards for protection of human subjects reviewing my research, and I further agree not to divulge any information obtained in the course of such research to unauthorized persons, and not to publish or otherwise make public any information regarding persons who have received services such that the person who received services is identifiable.

I recognize that the unauthorized release of confidential information may make me subject to a civil action under provisions of the Welfare and Institutions Code.

(f) To the courts, as necessary to the administration of justice.

(g) To governmental law enforcement agencies as needed for the protection of federal and state elective constitutional officers and their families.

(h) To the Committee on Senate Rules or the Committee on Assembly Rules for the purposes of legislative investigation authorized by the committee.

(i) If the recipient of services who applies for life or disability insurance designates in writing the insurer to which records or information may be disclosed.

(j) To the attorney for the patient in any and all proceedings upon presentation of a

release of information signed by the patient, except that when the patient is unable to sign the release, the staff of the facility, upon satisfying itself of the identity of the attorney, and of the fact that the attorney does represent the interests of the patient, may release all information and records relating to the patient except that nothing in this article shall be construed to compel a physician, licensed psychologist, social worker with a master's degree in social work, licensed marriage and family therapist, nurse, attorney, or other professional person to reveal information that has been given to him or her in confidence by members of a patient's family.

(k) Upon written agreement by a person previously confined in or otherwise treated by a facility, the professional person in charge of the facility or his or her designee may release any information, except information that has been given in confidence by members of the person's family, requested by a probation officer charged with the evaluation of the person after his or her conviction of a crime if the professional person in charge of the facility determines that the information is relevant to the evaluation. The agreement shall only be operative until sentence is passed on the crime of which the person was convicted. The confidential information released pursuant to this subdivision shall be transmitted to the court separately from the probation report and shall not be placed in the probation report. The confidential information shall remain confidential except for purposes of sentencing. After sentencing, the confidential information shall be sealed.

(l) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to subdivision (d) of Section 18951. The information and records sought to be disclosed shall be relevant to the prevention, identification, management, or treatment of an abused child and his or her parents pursuant to Chapter 11 (commencing with Section 18950) of Part 6 of Division 9.

(m) To county patients' rights advocates who have been given knowing voluntary authorization by a client or a guardian ad litem. The client or guardian ad litem, whoever entered into the agreement, may revoke the authorization at any time, either in writing or by oral declaration to an approved advocate.

(n) To a committee established in compliance with Sections 4070.

(o) In providing information as described in Section 7325.5. Nothing in this subdivision shall permit the release of any information other than that described in Section 7325.5."

(p) To the county mental health director or the director's designee, or to a law enforcement officer, or to the person designated by a law enforcement agency, pursuant to Sections 5152.1 and 5250.1."

(q) If the patient gives his or her consent, information specifically pertaining to the existence of genetically handicapping conditions, as defined in Section 125135 of the Health and Safety Code, may be released to qualified professional persons for purposes of genetic counseling for blood relatives upon request of the blood relative. For purposes of this subdivision, "qualified professional persons", means those persons with the qualifications necessary to carry out the genetic counseling duties under this subdivision as determined by the genetic disease unit established in the State Department of Health Services under Section 125000 of the Health and Safety Code. If the patient does not respond or cannot respond to a request for permission to release information pursuant to this subdivision after reasonable attempts have been made over a two-week period to get a response, the information may be released upon request of the blood relative.

(r) When the patient, in the opinion of his or her psychotherapist, presents a serious

danger of violence to a reasonably foreseeable victim or victims, then any of the information or records specified in this section may be released to that person or persons and to law enforcement agencies as the psychotherapist determines is needed for the protection of that person or persons. For purposes of this subdivision, "psychotherapist" means anyone so defined within Section 1010 of the Evidence Code.

(s) (1) To the designated officer of an emergency response employee, and from that designated officer to an emergency response employee regarding possible exposure to HIV or AIDS, but only to the extent necessary to comply with provisions of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(2) For purposes of this subdivision, "designated officer" and "emergency response employee" have the same meaning as these terms are used in the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (P.L. 101-381; 42 U.S.C. Sec. 201).

(3) The designated officer shall be subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV results. Further, the designated officer shall inform the exposed emergency response employee that the employee is also subject to the confidentiality requirements specified in Section 120980, and may be personally liable for unauthorized release of any identifying information about the HIV test results. (t) (1) To a law enforcement officer who personally lodges with a facility, as defined in paragraph (2), a warrant of arrest or an abstract of such a warrant showing that the person sought is wanted for a serious felony, as defined in Section 1192.7 of the Penal Code, or a violent felony, as defined in Section 667.5 of the Penal Code. The information sought and released shall be limited to whether or not the person named in the arrest warrant is presently confined in the facility. This paragraph shall be implemented with minimum disruption to health facility operations and patients, in accordance with Section 5212. If the law enforcement officer is informed that the person named in the warrant is confined in the facility, the officer may not enter the facility to arrest the person without obtaining a valid search warrant or the permission of staff of the facility.

(2) For purposes of paragraph (1), a facility means all of the following:

(A) A state hospital, as defined in Section 4001.

(B) A general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, solely with regard to information pertaining to a mentally disordered person subject to this section.

(C) An acute psychiatric hospital, as defined in subdivision (b) of Section 1250 of the Health and Safety Code.

(D) A psychiatric health facility, as described in Section 1250.2 of the Health and Safety Code.

(E) A mental health rehabilitation center, as described in Section 5675.

(F) A skilled nursing facility with a special treatment program for chronically mentally disordered patients, as described in Sections 51335 and 72445 to 72475, inclusive, of Title 22 of the California Code of Regulations.

(u) Between persons who are trained and qualified to serve on multidisciplinary personnel teams pursuant to Section 15610.55, 15753.5, or 15761. The information and records sought to be disclosed shall be relevant to the prevention, identification, management, or treatment of an abused elder or dependent adult pursuant to Chapter

13 (commencing with Section 15750) of Part 3 of Division 9.

(v) The amendment of subdivision (d) enacted at the 1970 Regular Session of the Legislature does not constitute a change in, but is declaratory of, the preexisting law.

(w) This section shall not be limited by Section 5150.05 or 5332.

(x) (1) When an employee is served with a notice of adverse action, as defined in Section 19570 of the Government Code, the following information and records may be released:

(A) All information and records that the appointing authority relied upon in issuing the notice of adverse action.

(B) All other information and records that are relevant to the adverse action, or that would constitute relevant evidence as defined in Section 210 of the Evidence Code.

(C) The information described in subparagraphs (A) and (B) may be released only if both of the following conditions are met:

(i) The appointing authority has provided written notice to the consumer and the consumer's legal representative or, if the consumer has no legal representative or if the legal representative is a state agency, to the clients' rights advocate, and the consumer, the consumer's legal representative, or the clients' rights advocate has not objected in writing to the appointing authority within five business days of receipt of the notice, or the appointing authority, upon review of the objection has determined that the circumstances on which the adverse action is based are egregious or threaten the health, safety, or life of the consumer or other consumers and without the information the adverse action could not be taken.

(ii) The appointing authority, the person against whom the adverse action has been taken, and the person's representative, if any, have entered into a stipulation that does all of the following:

(I) Prohibits the parties from disclosing or using the information or records for any purpose other than the proceedings for which the information or records were requested or provided.

(II) Requires the employee and the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee' s legal representative because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(III) Requires the parties to submit the stipulation to the administrative tribunal with jurisdiction over the adverse action at the earliest possible opportunity.

(2) For the purposes of this subdivision, the State Personnel Board may, prior to any appeal from adverse action being filed with it, issue a protective order, upon application by the appointing authority, for the limited purpose of prohibiting the parties from disclosing or using information or records for any purpose other than the proceeding for which the information or records were requested or provided, and to require the employee or the employee's legal representative to return to the appointing authority all records provided to them under this subdivision, including, but not limited to, all records and documents from any source containing confidential information protected by this

section, and all copies of those records and documents, within 10 days of the date that the adverse action becomes final, except for the actual records and documents or copies thereof that are no longer in the possession of the employee or the employee's legal representatives because they were submitted to the administrative tribunal as a component of an appeal from the adverse action.

(3) Individual identifiers, including, but not limited to, names, social security numbers, and hospital numbers, that are not necessary for the prosecution or defense of the adverse action, shall not be disclosed.

(4) All records, documents, or other materials containing confidential information protected by this section that has been submitted or otherwise disclosed to the administrative agency or other person as a component of an appeal from an adverse action shall, upon proper motion by the appointing authority to the administrative tribunal, be placed under administrative seal and shall not, thereafter, be subject to disclosure to any person or entity except upon the issuance of an order of a court of competent jurisdiction.

(5) For purposes of this subdivision, an adverse action becomes final when the employee fails to answer within the time specified in Section 19575 of the Government Code, or, after filing an answer, withdraws the appeal, or, upon exhaustion of the administrative appeal or of the judicial review remedies as otherwise provided by law.

HIPAA

42 United States Code Sections 290dd-2(g) Confidentiality of Records

(g) Regulations

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

42 CFR § 2.1

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified at 42 U.S.C. 290ee-3. The amended statutory authority is set forth below:

Sec. 290ee-3. Confidentiality of patient records.

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient

regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefore. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician- patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records--

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures,

including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

42 C.F.R. section 2.31: Form of written consent.

(a) Required elements. A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under Sec. 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under Sec. 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) Sample consent form. The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) Request Authorize:

2. (name or general designation of program which is to make the disclosure)

_____

3. To disclose: (kind and amount of information to be disclosed)

_____

4. To: (name or title of the person or organization to which disclosure is to be made)

_____

5. For (purpose of the disclosure)

_____

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

9. Signature of person authorized to sign in lieu of the patient (where required)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) Expired, deficient, or false consent. A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

42 CFR Part 2.32: Prohibition on re-disclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

45 C.F.R. section 164.502(a): Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with §164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §164.502(b), §164.514(d), and §164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under §164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and

(vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by §164.524 or §164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

45 C.F.R. section 164.508: Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*

(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

(3) *Authorization required: Marketing.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: General requirements*

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not

inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the

extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by §164.530(j).

(c) *Implementation specifications: Core elements and requirements*.

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by §164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to

re-disclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization

45 C.F.R. section 164.512(c): Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence*

(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

Scenario 18	**Health Oversight, Immunization & Lead Poisoning** The Governor's office has expressed concern about compliance with immunization and lead screening requirements among low-income children who do not receive consistent health care. The state agencies responsible for public health, child welfare and protective services, Medicaid services, and education are asked to share identifiable patient level health care data on an ongoing basis to determine if the children are getting the healthcare they need. This is not part of a legislative mandate. The Governor in this state and those in the surrounding states have discussed sharing this information to determine if patients migrate between states for these services. Because of the complexity of the task, the Governor has asked each agency to provide these data to faculty at the state university medical campus who will design a system for integrating and analyzing the data. There is not existing contract with the state university for services of this nature.
Summary	In depicting a reasonably plausible situation, this scenario illustrates the complexity of the process of identifying all relevant law and the lengthy analysis required to determine the interaction between the laws. This scenario shows that a large amount of attorney research in diverse areas must be conducted to understand how to operate. In addition, the disclosures examined in scenario 18 are covered by the State's general information privacy laws—the IPA and CMIA. A number of potentially applicable IPA/CMIA restrictions and/or exemptions from the general rules would have to be analyzed. Finally, in this scenario a number of federal and state laws governing the disclosure of information from State agency programs (e.g., Medicaid, child protective services, etc.) would require analyses.
Immunization: **State Law**	**Specific immunization-related laws:** • Health and Safety Code section 120325, et seq., creates the immunization requirements for educational and child care facilities, for the eventual achievement of total immunizations • Health and Safety Code section 120440, deals with the disclosure of immunization status • Health and Safety Code section 124030 et seq. creates the Child Health and Disability Prevention Program • Education Code section 49075 and 49076, deals with the privacy of pupil records and requiring consent of the parents in order for the records to be disclosed. • Education Code section 49062 provides that pupil records include pupil's health records. • 5 California Code of Regulations section 432 provides that immunizations are to be included in the mandatory permanent pupil record, a type of pupil records. The Child Health and Disability Prevention Program, which DHS has deemed as being a covered entity health plan. It is a program for counties to have early assessments of the health status of children in which they would do health screening and evaluation services which include immunizations appropriate for the child's age and health history. Section 124110 provides confidentiality of the information and results of the health screening and evaluation. This is also a program that deals with Medi-Cal, and so would probably fall

	under the general Medi-Cal confidentiality laws. IPA • 1798.74 provides that the provisions of Chapter 13 of Part 40 of the Education Code, starting with section 67110, prevails over the IPA. Yet. Chapter 13 of the Education Code was repealed in 1995, as a result, the IPA would probably be applicable to student records.
HIPAA rule	Family Educational Rights and Privacy Act (FERPA) HIPAA has excluded education records covered by FERPA. The education records would be only those records from primary or secondary schools that receive federal funds, and are not considered protected health information. If a school does not receive federal funds, it is not an educational agency defined by FERPA and therefore the educational records that contain the individually identifiable health information may be protected health information and therefore may fall under HIPAA.
Lead Screening: **State Law**	This scenario illustrates the complexity of the process of identifying all relevant law and the type of lengthy analysis required to determine the interaction between the laws. This scenario shows, in essence, that some health information transmission activities simply cannot be legally understood without a large amount of attorney research. CLPPA mandates only DHS as the regulator of child lead screening requirements and compliance. Accordingly, no other State agency responsible for public health, child welfare and protective services, Medicaid services, or education would seem to be authorized to disclose PHI for purposes of regulating the screening program to the State university faculty or to any entity other than DHS (without authorization from each beneficiary). In California, DHS is responsible for most aspects of State regulated public health programs. Thus DHS would already possess the requested information. DHS is also the single state agency responsible for Medicaid in California (Medi-Cal). However, Medi-Cal has strict limits on the disclosure of beneficiary information—essentially the information can only be disclosed for purposes of the Medi-Cal program—not other purposes such as analyzing compliance with the Act. Most if not all of the public health programs have similar restrictions on disclosure, some of which are extremely restrictive (e.g., HIV-related PHI). It is likely that laws restricting access to program records also regulate other State agencies responsible for non-DHS-administered aspects of public health, for child welfare and protective services, and for education. Although DHS has both the broad regulatory authority to effectuate the lead screening program as well as the duty to collect and analyze all information necessary to effectively monitor program compliance, it is unclear without a full analysis of each of the relevant agency program disclosure laws whether this DHS data collection authority in CLPPA prevails over them and to what extent. Even if relevant agency program laws allow for disclosure to DHS without beneficiary authorization, it is uncertain as to whether there are provisions in the IPA or CMIA that would allow for these disclosures (or, conversely, provisions that restrict or bar them) and also what the status of those laws is relative to HIPAA preemption. It is possible, therefore, that each of the State agencies responsible for public health, child welfare and protective services, Medicaid services, and education, that are being ordered to disclose the information, would be barred from doing so without an authorization from each beneficiary (unless an applicable exception to the CMIA and IPA authorization requirement exists and is not preempted by HIPAA).

Even if relevant agency program laws and general State privacy laws allow for disclosure to DHS without beneficiary authorization, it is uncertain as to whether DHS would be authorized to delegate its collection and analysis duties to the State University. There is no authority in CLPPA authorizing DHS to do so. DHS may have authority to contract out for this function, but that requires a separate analysis. [NOTE: Pursuant to IPA § 1798.19, any contractor of these State agencies must also abide by the IPA.]

Specific lead screening-related laws:

- Health and Safety Code section 105275, et seq., the Childhood Lead Poisoning Prevention Act of 1991 (CLPPA) regulate this function.
- Health and Safety Code section 124125, subsection (a), requires the Childhood Lead Poisoning Prevention Program "[t]o compile information concerning the prevalence, causes, and geographic occurrence of high childhood blood lead levels."
- [NOTE: There are also regulations associated with CLPPA—however they outline the standard of care for providers and are not relevant to the analysis of this scenario.]

General use and disclosure laws:

Information Practices Act and Confidentiality of Medical Information Act

- Each of the State agencies responsible for public health, child welfare and protective services, Medicaid services, and education, are subject to the Information Practices Act of 1977 (IPA) (Civ. Code § 1798, et seq.) Some of these agencies are also regulated by the Confidentiality of Medical Information Act (CMIA) (Civ. Code § 56, et seq.)
- This distinction is negated, however, by Section 56.29(a) of the CMIA, which mandates cross-restrictions on disclosure of medical information between the CMIA and the IPA ("Nothing in [the IPA] shall be construed to permit the acquisition or disclosure of medical information regarding a patient without an authorization, where the authorization is required by [the CMIA]").
- An undetermined number of potentially-applicable IPA/CMIA restrictions and/or exemptions from general rule requiring authorization (see Discussion section below). [NOTE: Each of these provisions must be independently analyzed for preemption or partial preemption by HIPAA.]

Other law:

- An undetermined number of laws governing the disclosure of information from programs of the State agencies responsible for public health, child welfare and protective services, Medicaid services, and education, also require analysis (see Discussion section below). [NOTE: Each of these provisions must be independently analyzed for preemption or partial preemption by HIPAA.]

HIPAA rule

HIPAA preemption of specific lead screening-related laws:

- According to DHS, although these specific lead screening related laws relate to confidentiality and privacy, they are not subject to HIPAA preemption analysis because the program regulated by the laws—DHS' Childhood Lead Program—is not a HIPAA-covered entity. (See, *DHS. Response to 1/14/02 Memo from Irene*

Tamura (March, 13, 2002), subject: Identification of State Law Relating to Confidentiality and/or Privacy of Personal Information, Questionnaire Regarding Identified State Health Information Privacy Laws and HIPAA.)

Citations:

State

Civil Code section 56.29(a)

(a) Nothing in Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 shall be construed to permit the acquisition or disclosure of medical information regarding a patient without an authorization, where the authorization is required by this part.

Health and Safety Code section 105275, et seq

105275. This chapter shall be known, and may be cited as, the Childhood Lead Poisoning Prevention Act of 1991.

105280. For purposes of this chapter, the following definitions apply:

(a) "Appropriate case management" means health care referrals, environmental assessments, and educational activities, performed by the appropriate person, professional, or entity, necessary to reduce a child's exposure to lead and the consequences of the exposure, as determined by the United States Centers for Disease Control, or as determined by the department pursuant to Section 105300.

(b) "Lead poisoning" means the disease present when the concentration of lead in whole venous blood reaches or exceeds levels constituting a health risk, as specified in the most recent United States Centers for Disease Control guidelines for lead poisoning as determined by the department, or when the concentration of lead in whole venous blood reaches or exceeds levels constituting a heath risk as determined by the department pursuant to Section 105300.

(c) "Department" means the State Department of Health Services.

(d) "Health assessment" has the same meaning as prescribed in Section 6800 of Title 17 of the California Code of Regulations.

(e) "Screen" means the medical procedure by which the concentration of lead in whole venous blood is measured.

(f) "Health care" means the identification, through evaluation and screening, if indicated, of lead poisoning, as well as any follow-up medical treatment necessary to reduce the elevated blood lead levels.

(g) "Environmental lead contamination" means the persistent presence of lead in the environment, in quantifiable amounts, that results in ongoing and chronic exposure to children.

105285. (a) After July 1, 1992, but on or before July 1, 1993, the department shall adopt regulations establishing a standard of care, at least as stringent as the most recent United States Centers for Disease Control screening guidelines, whereby all children shall be evaluated for risk of lead poisoning by health care providers during each child's periodic health assessment. The regulations shall be developed in consultation with medical experts, environmental experts, appropriate professional organizations, and the public, as determined by the department.

(b) The standard of care shall provide that, upon evaluation, those children determined to be "at risk" for lead poisoning, according to the regulations adopted pursuant to subdivision (a), shall be screened.

(c) The standard of care shall provide that no child shall be screened pursuant to this article if the parent or guardian of the child refuses to consent to the screening.

(d) The standard of care shall provide that health care providers shall be responsible only for evaluation of all children, for screening of children determined to be at risk, and for medically necessary follow-up services.

(e) The standard of care established pursuant to this section shall not become operative before April 1, 1993.

105290. On or after April 1, 1993, in those instances in which a child is identified with lead poisoning, the department shall ensure appropriate case management. The department may contract with any public or private entity, including local agencies, to conduct the case management.

105291. In addition to any other providers determined to be eligible by the department to provide environmental investigation services as a part of case management services under this chapter, a qualified certified industrial hygienist or other qualified professional who is certified by the department as an inspector/assessor shall be eligible to provide those services and those services shall be funded under the Childhood Lead Poisoning Prevention Program pursuant to this chapter.

105295. The department shall collect and analyze all information necessary to effectively monitor appropriate case management efforts.

The department shall prepare a biennial report describing the effectiveness of appropriate case management efforts. This report shall be made available to local health departments and the general public.

105300. Notwithstanding Section 124130, the department shall have broad regulatory authority to fully implement and effectuate the purposes of this chapter. The authority shall include, but is not limited to, the following:

(a) The development of protocols to be utilized in screening and the procedures for changing those protocols when more accurate or efficient technologies become available.

(b) The designation of laboratories which are qualified to analyze whole blood specimens for concentrations of lead and the monitoring of those laboratories for accuracy.

(c) The development of reporting procedures by laboratories.

(d) Reimbursement for state-sponsored services related to screening and appropriate case management.

(e) Establishment of lower concentrations of lead in whole blood than those specified by the United States Centers for Disease Control for the purpose of determining the existence of lead poisoning.

(f) Establishment of lower acceptable levels of the concentration of lead in whole blood than those specified by the United States Centers for Disease Control for the purpose of determining the need to provide appropriate case management for lead poisoning.

(g) Development of appropriate case management protocols.

(h) Notification to the child's parent or guardian of the results of blood lead testing and environmental assessment.

(i) The establishment of a periodicity schedule for evaluation for childhood lead

poisoning.

105305. The program implemented pursuant to this chapter shall be fully supported from the fees collected pursuant to Section 105310. Notwithstanding the scope of activity mandated by this chapter, in no event shall this chapter be interpreted to require services necessitating expenditures in any fiscal year in excess of the fees, and earnings there from, collected pursuant to Section 105310. This chapter shall be implemented only to the extent fee revenues pursuant to Section 105310 are available for expenditure for purposes of this chapter.

105310. (a) There is hereby imposed a fee on manufacturers and other persons formerly, presently, or both formerly and presently engaged in the stream of commerce of lead or products containing lead, or who are otherwise responsible for identifiable sources of lead, which have significantly contributed historically, currently contribute, or both have significantly contributed historically and contribute currently to environmental lead contamination.

(b) After July 1, 1992, but on or before January 1, 1993, the department shall, by regulation, establish specific fees to be assessed on manufacturers and other parties formerly, presently, or both formerly and presently engaged in the stream of commerce of lead or products containing lead, or who are otherwise responsible for identifiable sources of lead which, as determined by the department, have significantly contributed historically, currently contribute, or both have significantly contributed historically and contribute currently to environmental lead contamination.

To the maximum extent practicable, the fees shall be assessed on the basis of the following criteria:

(1) A person's past and present responsibility for environmental lead contamination.

(2) A person's "market share" responsibility for environmental lead contamination.

This section shall not apply to, and no fee shall be assessed upon, any retailer of lead or products containing lead.

(c) The fee shall be assessed and collected annually by the State Board of Equalization. The first payment of these fees shall be due on or before April 1, 1993. The annual fee assessment in subdivision (a) shall be adjusted by the department to reflect both of the following:

(1) The increase in the annual average of the California Consumers Price Index, as recorded by the California Department of Industrial Relations, for the most recent year available.

(2) The increase or decrease in the number of children in California who are receiving services pursuant to this article.

This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) (1) No fee shall be assessed upon a person if that person can demonstrate, as determined by the department, that his or her industry did not contribute in any manner, as described in this section, to environmental lead contamination.

(2) No fee shall be assessed upon a party if that party demonstrates, as determined by the department, that the lead, or the product containing lead, with which it is currently, or was historically, associated does not currently, or did not historically, result in quantifiably persistent environmental lead contamination.

(e) The fee imposed pursuant to this section shall be administered and collected by the board of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees shall be deposited in the Childhood Lead Poisoning Prevention Fund, which is hereby created in the State Treasury. Moneys in the fund shall be expended for the purposes of this chapter, including the State Board of Equalization's costs of collection and administration of fees, upon appropriation by the Legislature. All interest earned on the moneys which have been deposited into the Childhood Lead Poisoning Prevention Fund shall be retained in that fund.

(f) The fees collected pursuant to this section and the earnings there from shall be used solely for the purposes of implementing this chapter. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this chapter. The department shall not spend more than it collects from the fees and the earnings in implementing this chapter. In no fiscal year shall the department collect more than sixteen million dollars ($16,000,000) in fees, as adjusted for inflation pursuant to subdivision (b).

(g) It is the intent of the Legislature, in subsequent legislation, to appropriate and deposit into the Childhood Lead Poisoning Prevention Fund the sum of one hundred twenty-eight thousand dollars ($128,000) from the General Fund on July 1, 1992, to the Controller for allocation as loans as follows:

(1) Seventy-eight thousand dollars ($78,000) to the department, for the purposes of adopting regulations to establish the fee schedule authorized by this section. The State Board of Equalization shall repay the amount of this appropriation, on or before June 30, 1993, with interest at the pooled money investment rate, from fees collected pursuant to this section.

(2) Fifty thousand dollars ($50,000) to the State Board of Equalization, for the purposes of implementing this section. The State Board of Equalization shall repay the amount of this appropriation on or before June 30, 1993, with interest at the pooled money investment rate, from fees collected pursuant to this section.

(h) Regulations adopted for fee assessment and collection pursuant to this section shall be exempt from review by the Office of Administrative Law.

Health and Safety Code section 120325, et seq.,

120325. In enacting Chapter 1 (commencing with Section 120325, but excluding Section 120380) and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide:

(a) A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:

(1) Diphtheria.

(2) Hepatitis B.

(3) Haemophilus influenzae type b.

(4) Measles.

(5) Mumps.

(6) Pertussis (whooping cough).

(7) Poliomyelitis.

(8) Rubella.

(9) Tetanus.

(10) Varicella (chickenpox). This paragraph shall be operative only to the extent that funds for this purpose are appropriated in the annual Budget Act.

(11) Any other disease that is consistent with the most current recommendations of the United States Public Health Services' Centers for Disease Control Immunization Practices Advisory Committee and the American Academy of Pediatrics Committee of Infectious Diseases, and deemed appropriate by the department.

(b) That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.

(c) Exemptions from immunization for medical reasons or because of personal beliefs.

(d) For the keeping of adequate records of immunization so that health departments, schools, and other institutions, parents or guardians, and the persons immunized will be able to ascertain that a child is fully or only partially immunized, and so that appropriate public agencies will be able to ascertain the immunization needs of groups of children in schools or other institutions.

(e) Incentives to public health authorities to design innovative and creative programs that will promote and achieve full and timely immunization of children.

120330. The department, in consultation with the Department of Education, shall adopt and enforce all regulations necessary to carry out Chapter 1 (commencing with Section 120325, but excluding Section 120380) and to carry out Sections 120400, 120405, 120410, and 120415.

120335. (a) As used in Chapter 1 (commencing with Section 120325, but excluding Section 120380), and as used in Sections 120400, 120405, 120410, and 120415, the term "governing authority" means the governing board of each school district or the authority of each other private or public institution responsible for the operation and control of the institution or the principal or administrator of each school or institution.

(b) The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless prior to his or her first admission to that institution he or she has been fully immunized. The following are the diseases for which immunizations shall be documented:

(1) Diphtheria.

(2) Haemophilus influenzae type b, except for children who have reached the age of four years and six months.

(3) Measles.

(4) Mumps, except for children who have reached the age of seven years.

(5) Pertussis (whooping cough), except for children who have reached the age of seven years.

(6) Poliomyelitis.

(7) Rubella.

(8) Tetanus.

(9) Hepatitis B for all children entering the institutions listed in this subdivision at the

kindergarten level or below on or after August 1, 1997.

(10) Varicella (chickenpox), effective July 1, 2001. Persons already admitted into California public or private schools at the kindergarten level or above before July 1, 2001, shall be exempt from the varicella immunization requirement for school entry. This paragraph shall be operative only to the extent that funds for this purpose are appropriated in the annual Budget Act.

The department may adopt emergency regulations to implement this paragraph including, but not limited to, requirements for documentation and immunization status reports, in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The initial adoption of emergency regulations shall be deemed to be an emergency and considered by the Office of Administrative Law as necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted pursuant to this paragraph shall remain in effect for no more than 180 days.

(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the United States Public Health Services' Centers for Disease Control Immunization Practices Advisory Committee and the American Academy of Pediatrics Committee of Infectious Diseases.

(c) On and after July 1, 1999, the governing authority shall not unconditionally admit any pupil to the 7th grade level, nor unconditionally advance any pupil to the 7th grade level, of any of the institutions listed in subdivision (b) unless the pupil has been fully immunized against hepatitis B.

(d) The department may specify the immunizing agents which may be utilized and the manner in which immunizations are administered.

Health and Safety Code section 120440

(a) For the purposes of this chapter, the following definitions shall apply:

(1) "Health care provider" means any person licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code or a clinic or health facility licensed pursuant to Division 2 (commencing with Section 1200).

(2) "Schools, child care facilities, and family child care homes" means those institutions referred to in subdivision (b) of Section 120335, regardless of whether they directly provide immunizations to patients or clients.

(3) "WIC service provider" means any public or private nonprofit agency contracting with the department to provide services under the California Special Supplemental Food Program for Women, Infants, and Children, as provided for in Article 2 (commencing with Section 123275) of Chapter 1 of Part 2 of Division 106.

(4) "Health care plan" means a health care service plan as defined in subdivision (f) of Section 1345, a government-funded program the purpose of which is paying the costs of health care, or an insurer as described in Sections 10123.5 and 10123.55 of the Insurance Code, regardless of whether the plan directly provides immunizations to patients or clients.

(5) "County welfare department" means a county welfare agency administering the California Work Opportunity and Responsibility to Kids (CalWORKs) program, pursuant to Chapter 2 (commencing with Section 11200.5) of Part 3 of Division 9 of the Welfare and Institutions Code.

(6) "Foster care agency" means any of the county and state social services agencies providing foster care services in California.

(b) (1) Local health officers may operate immunization information systems pursuant to their authority under Section 120175, in conjunction with the Immunization Branch of the State Department of Health Services. Local health officers and the State Department of Health Services may operate these systems in either or both of the following manners:

(A) Separately within their individual jurisdictions.

(B) Jointly among more than one jurisdiction.

(2) Nothing in this subdivision shall preclude local health officers from sharing the information set forth in paragraphs (1) to (9), inclusive, of subdivision (c) with other health officers jointly operating the system.

(c) Notwithstanding Sections 49075 and 49076 of the Education Code, Chapter 5 (commencing with Section 10850) of Part 2 of Division 9 of the Welfare and Institutions Code, or any other provision of law, unless a refusal to permit record sharing is made pursuant to subdivision (e), health care providers, and other agencies, including, but not limited to, schools, child care facilities, service providers for the California Special Supplemental Food Program for Women, Infants, and Children (WIC), health care plans, foster care agencies, and county welfare departments, may disclose the information set forth in paragraphs (1) to (9), inclusive, from the patient's medical record, or the client's record, to local health departments operating countywide or regional immunization information and reminder systems and the State Department of Health Services. Local health departments and the State Department of Health Services may disclose the information set forth in paragraphs (1) to (9), inclusive, to each other, and upon a request for information pertaining to a specific person, to health care providers taking care of the patient. Local health departments and the State Department of Health Services may disclose the information in paragraphs (1) to (6), inclusive, and paragraphs (8) and (9), to schools, child care facilities, county welfare departments, and family child care homes to which the person is being admitted or in attendance, foster care agencies in assessing and providing medical care for children in foster care, and WIC service providers providing services to the person, health care plans arranging for immunization services for the patient, and county welfare departments assessing immunization histories of dependents of CalWORKs participants, upon request for information pertaining to a specific person. Determination of benefits based upon immunization of a dependent CalWORKs participant shall be made pursuant to Section 11265.8 of the Welfare and Institutions Code. The following information shall be subject to this subdivision:

(1) The name of the patient or client and names of the parents or guardians of the patient or client.

(2) Date of birth of the patient or client.

(3) Types and dates of immunizations received by the patient or client.

(4) Manufacturer and lot number for each immunization received.

(5) Adverse reaction to immunizations received.

(6) Other non-medical information necessary to establish the patient's or client's unique identity and record.

(7) Current address and telephone number of the patient or client and the parents or guardians of the patient or client.

(8) Patient's or client's gender.

(9) Patient's or client's place of birth.

(d) (1) Health care providers, local health departments, and the State Department of Health Services shall maintain the confidentiality of information listed in subdivision (c) in the same manner as other medical record information with patient identification that they possess. These providers, departments, and contracting agencies are subject to civil action and criminal penalties for the wrongful disclosure of the information listed in subdivision (c), in accordance with existing law. They shall use the information listed in subdivision (c) only for the following purposes:

(A) To provide immunization services to the patient or client, including issuing reminder notifications to patients or clients or their parents or guardians when immunizations are due.

(B) To provide or facilitate provision of third-party payer payments for immunizations.

(C) To compile and disseminate statistical information of immunization status on groups of patients or clients or populations in California, without identifying information for these patients or clients included in these groups or populations.

(D) In the case of health care providers only, as authorized by Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(2) Schools, child care facilities, family child care homes, WIC service providers, foster care agencies, county welfare departments, and health care plans shall maintain the confidentiality of information listed in subdivision (c) in the same manner as other client, patient, and pupil information that they possess. These institutions and providers are subject to civil action and criminal penalties for the wrongful disclosure of the information listed in subdivision (c), in accordance with existing law. They shall use the information listed in subdivision (c) only for those purposes provided in subparagraphs (A) to (D), inclusive, of paragraph (1) and as follows:

(A) In the case of schools, child care facilities, family child care homes, and county welfare departments, to carry out their responsibilities regarding required immunization for attendance or participation benefits, or both, as described in Chapter 1 (commencing with Section 120325), and in Section 11265.8 of the Welfare and Institutions Code.

(B) In the case of WIC service providers, to perform immunization status assessments of clients and to refer those clients found to be due or overdue for immunizations to health care providers.

(C) In the case of health care plans, to facilitate payments to health care providers, to assess the immunization status of their clients, and to tabulate statistical information on the immunization status of groups of patients, without including patient-identifying information in these tabulations.

(D) In the case of foster care agencies, to perform immunization status assessments of foster children and to assist those foster children found to be due or overdue for immunization in obtaining immunizations from health care providers.

(e) A patient or a patient's parent or guardian may refuse to permit record sharing. The health care provider administering immunization and any other agency possessing any patient or client information listed in subdivision (c), if planning to provide patient or client information to an immunization system, as described in subdivision (b), shall inform the patient or client, or the parent or guardian of the patient or client, of the following:

(1) The information listed in subdivision (c) may be shared with local health departments, and the State Department of Health Services. The health care provider or

other agency shall provide the name and address of the State Department of Health Services and of the immunization registry with which the provider or other agency will share the information.

(2) Any of the information shared with local health departments and the State Department of Health Services shall be treated as confidential medical information and shall be used only to share with each other, and, upon request, with health care providers, schools, child care facilities, family child care homes, WIC service providers, county welfare departments, foster care agencies, and health care plans. These providers, agencies, and institutions shall, in turn, treat the shared information as confidential, and shall use it only as described in subdivision (d).

(3) The patient or client, or parent or guardian of the patient or client, has the right to examine any immunization-related information shared in this manner and to correct any errors in it.

(4) The patient or client, or the parent or guardian of the patient or client, may refuse to allow this information to be shared in the manner described, or to receive immunization reminder notifications at any time, or both.

(f) (1) The health care provider administering the immunization and any other agency possessing any patient or client information listed in subdivision (c) may inform the patient or client, or the parent or guardian of the patient or client, by ordinary mail, of the information in paragraphs (1) to (4), inclusive, of subdivision (e). The mailing must include a reasonable means for refusal, such as a return form or contact telephone number.

(2) The information in paragraphs (1) to (4), inclusive, of subdivision (e) may also be presented to the parent or guardian of the patient or client during any hospitalization of the patient or client.

(g) If the patient or client, or parent or guardian of the patient or client, refuses to allow the information to be shared, pursuant to paragraph (4) of subdivision (e), the health care provider or other agency may not share this information in the manner described in subdivision (c), except as provided in subparagraph (D) of paragraph (1) of subdivision (d).

(h) Upon request of the patient or client, or the parent or guardian of the patient or client, in writing or by other means acceptable to the recipient, a local health department or the State Department of Health Services that has received information about a person pursuant to subdivision (c) shall do all of the following:

(1) Provide the name and address of other persons or agencies with whom the recipient has shared the information.

(2) Stop sharing the information in its possession after the date of the receipt of the request.

(i) Upon notification, in writing or by other means acceptable to the recipient, of an error in the information, a local health department or the State Department of Health Services that has information about a person pursuant to subdivision (c) shall correct the error. If the recipient is aware of a disagreement about whether an error exists, information to that effect may be included.

(j) (1) Any party authorized to make medical decisions for a patient or client, including, but not limited to, those authorized by Section 6922, 6926, or 6927 of, or Part 1.5 (commencing with Section 6550), Chapter 2 (commencing with Section 6910) of Part 4, or Chapter 1 (commencing with Section 7000) of Part 6 of Division 11 of, the Family

Code, Section 1530.6 of the Health and Safety Code, or Sections 727 and 1755.3 of, and Article 6 (commencing with Section 300) of Chapter 2 of Part 1 of Division 2 of, the Welfare and Institutions Code, may permit sharing of the patient's or client's record with any of the immunization information systems authorized by this section.

(2) For a patient or client who is a dependent of a juvenile court, the court or a person or agency designated by the court may permit this record sharing.

(3) For a patient or client receiving foster care, a person or persons licensed to provide residential foster care, or having legal custody, may permit this record sharing.

(k) For purposes of supporting immunization information systems, the State Department of Health Services shall assist its Immunization Branch in both of the following:

(1) Providing department records containing information about publicly funded immunizations.

(2) Supporting efforts for the reporting of publicly funded immunizations into immunization information systems by health care providers and health care plans.

(l) Section 120330 shall not apply to this section.

Health and Safety Code section 124030

As used in this article and Section 120475:

(a) "State board" means the State Maternal, Child, and Adolescent Health Board.

(b) "Department" means the department.

(c) "Director" means the director.

(d) "Governing body" means the county board of supervisors or boards of supervisors in the case of counties acting jointly.

(e) "Local board" means local maternal, child, and adolescent health board.

(f) "Local health jurisdiction" means county health department or combined health department in the case of counties acting jointly or city health department within the meaning of Section 101185.

(g) "Child Health and Disability Prevention provider" or "CHDP provider" means any of the following, if approved for participation in the Child Health and Disability Prevention program by the community Child Health and Disability program director in accordance with program standards and as certified by the department:

(1) A physician licensed to practice medicine in California.

(2) A family nurse practitioner certified pursuant to Section 2834 and 2836 of the Business and Professions Code.

(3) A pediatric nurse practitioner certified pursuant to Sections 2834 and 2836 of the Business and Professions Code.

(4) A primary care center, clinic, or other public or private agency or organization that provides outpatient health care services.

(5) A physicians' group.

(6) A licensed clinical laboratory.

Health and Safety Code section 124110

124110. All information and results of the health screening and evaluation of each child shall be confidential and shall not be released without the informed consent of a parent

or guardian of the child.

The results of the health screening and evaluation shall not be released to any public or private agency, even with the consent of a parent or guardian, unless accompanied by a professional interpretation of what the results mean.

Health and Safety Code section 124125(a)

The Legislature hereby finds and declares that childhood lead exposure represents the most significant childhood environmental health problem in the state today; that too little is known about the prevalence, long-term health care costs, severity, and location of these problems in California; that it is well known that the environment is widely contaminated with lead; that excessive lead exposure causes acute and chronic damage to a child's renal system, red blood cells, and developing brain and nervous system; that at least one in every 25 children in the nation has an elevated blood lead level; and that the cost to society of neglecting this problem may be enormous.

The Legislature further finds and declares that knowledge about where and to what extent harmful childhood lead exposures are occurring in the state could lead to the prevention of these exposures, and to the betterment of the health of California's future citizens. Therefore, it is the intent of the Legislature in enacting this article to establish a state Childhood Lead Poisoning Prevention Program within the department to accomplish all of the following:

(a) To compile information concerning the prevalence, causes, and geographic occurrence of high childhood blood lead levels.

Education Code section 49062

School districts shall establish, maintain, and destroy pupil records according to regulations adopted by the State Board of Education. Pupil records shall include a pupil's health record. Such regulations shall establish state policy as to what items of information shall be placed into pupil records and what information is appropriate to be compiled by individual school officers or employees under the exception to pupil records provided in subdivision (b) of Section 49061. No pupil records shall be destroyed except pursuant to such regulations or as provided in subdivisions (b) and (c) of Section 49070.

Education Code section 49075 and 49076

49075. (a) A school district may permit access to pupil records to any person for whom a parent of the pupil has executed written consent specifying the records to be released and identifying the party or class of parties to whom the records may be released. The recipient must be notified that the transmission of the information to others without the written consent of the parent is prohibited. The consent notice shall be permanently kept with the record file.

(b) Notwithstanding subdivision (a), school lunch applications and information shared pursuant to Section 49557.2 shall be retained by any school district in the manner most useful to the administration of the school lunch program.

49076. A school district is not authorized to permit access to pupil records to any person without written parental consent or under judicial order except that:

(a) Access to those particular records relevant to the legitimate educational interests of the requester shall be permitted to the following:

(1) School officials and employees of the district, members of a school attendance review board appointed pursuant to Section 48321, and any volunteer aide, 18 years of

age or older, who has been investigated, selected, and trained by a school attendance review board for the purpose of providing follow-up services to pupils referred to the school attendance review board, provided that the person has a legitimate educational interest to inspect a record.

(2) Officials and employees of other public schools or school systems, including local, county, or state correctional facilities where educational programs leading to high school graduation are provided or where the pupil intends to or is directed to enroll, subject to the rights of parents as provided in Section 49068.

(3) Authorized representatives of the Comptroller General of the United States, the Secretary of Education, and administrative head of an education agency, state education officials, or their respective designees, or the United States Office of Civil Rights, where the information is necessary to audit or evaluate a state or federally supported education program or pursuant to a federal or state law, provided that except when collection of personally identifiable information is specifically authorized by federal law, any data collected by those officials shall be protected in a manner which will not permit the personal identification of pupils or their parents by other than those officials, and any personally identifiable data shall be destroyed when no longer needed for the audit, evaluation, and enforcement of federal legal requirements.

(4) Other state and local officials to the extent that information is specifically required to be reported pursuant to state law adopted prior to November 19, 1974.

(5) Parents of a pupil 18 years of age or older who is a dependent as defined in Section 152 of the Internal Revenue Code of 1954.

(6) A pupil 16 years of age or older or having completed the 10th grade who requests access.

(7) Any district attorney who is participating in or conducting a truancy mediation program pursuant to Section 48263.5, or Section 601.3 of the Welfare and Institutions Code, or participating in the presentation of evidence in a truancy petition pursuant to Section 681 of the Welfare and Institutions Code.

(8) A prosecuting agency for consideration against a parent or guardian for failure to comply with the Compulsory Education Law (Chapter 2 (commencing with Section 48200) of Part 27) or with Compulsory Continuation Education (Chapter 3 (commencing with Section 48400) of Part 27).

(9) Any probation officer or district attorney for the purposes of conducting a criminal investigation or an investigation in regards to declaring a person a ward of the court or involving a violation of a condition of probation.

(10) Any judge or probation officer for the purpose of conducting a truancy mediation program for a pupil, or for purposes of presenting evidence in a truancy petition pursuant to Section 681 of the Welfare and Institutions Code. The judge or probation officer shall certify in writing to the school district that the information will be used only for truancy purposes. A school district releasing pupil information to a judge or probation officer pursuant to this paragraph shall inform, or provide written notification to, the parent or guardian of the pupil within 24 hours of the release of the information.

(11) Any county placing agency for the purpose of fulfilling the requirements of the health and education summary required pursuant to Section 16010 of the Welfare and Institutions Code or for the purpose of fulfilling educational case management responsibilities required by the juvenile court or by law and to assist with the school transfer or enrollment of a pupil. School districts, county offices of education, and county

placing agencies may develop cooperative agreements to facilitate confidential access to and exchange of the pupil information by electronic mail, facsimile, electronic format, or other secure means.

(b) School districts may release information from pupil records to the following:

(1) Appropriate persons in connection with an emergency if the knowledge of the information is necessary to protect the health or safety of a pupil or other persons.

(2) Agencies or organizations in connection with the application of a pupil for, or receipt of, financial aid. However, information permitting the personal identification of a pupil or his or her parents may be disclosed only as may be necessary for purposes as to determine the eligibility of the pupil for financial aid, to determine the amount of the financial aid, to determine the conditions which will be imposed regarding the financial aid, or to enforce the terms or conditions of the financial aid.

(3) The county elections official, for the purpose of identifying pupils eligible to register to vote, and for conducting programs to offer pupils an opportunity to register to vote. The information, however, shall not be used for any other purpose or given or transferred to any other person or agency.

(4) Accrediting associations in order to carry out their accrediting functions.

(5) Organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction, if the studies are conducted in a manner that will not permit the personal identification of pupils or their parents by persons other than representatives of the organizations and the information will be destroyed when no longer needed for the purpose for which it is obtained.

(6) Officials and employees of private schools or school systems where the pupil is enrolled or intends to enroll, subject to the rights of parents as provided in Section 49068. This information shall be in addition to the pupil's permanent record transferred pursuant to Section 49068.

A person, persons, agency, or organization permitted access to pupil records pursuant to this section may not permit access to any information obtained from those records by any other person, persons, agency, or organization without the written consent of the pupil's parent. However, this paragraph does not require prior parental consent when information obtained pursuant to this section is shared with other persons within the educational institution, agency, or organization obtaining access, so long as those persons have a legitimate interest in the information.

(c) Notwithstanding any other provision of law, any school district, including any county office of education or superintendent of schools, may participate in an interagency data information system that permits access to a computerized database system within and between governmental agencies or districts as to information or records which are non-privileged, and where release is authorized as to the requesting agency under state or federal law or regulation, if each of the following requirements are met:

(1) Each agency and school district shall develop security procedures or devices by which unauthorized personnel cannot access data contained in the system.

(2) Each agency and school district shall develop procedures or devices to secure privileged or confidential data from unauthorized disclosure.

(3) Each school district shall comply with the access log requirements of Section 49064.

(4) The right of access granted shall not include the right to add, delete, or alter data without the written permission of the agency holding the data.

(5) An agency or school district may not make public or otherwise release information on an individual contained in the database where the information is protected from disclosure or release as to the requesting agency by state or federal law or regulation.

5 California Code of Regulations section 432 Varieties of Pupil Records

(a) The principal of each school shall keep on file a record of enrollment and scholarship for each pupil currently enrolled in said school.
(b) Local school districts shall not compile any other pupil records except mandatory or permitted records as herein defined:

(1) “Mandatory Permanent Pupil Records" are those records which the schools have been directed to compile by California statute authorization or authorized administrative directive. Each school district shall maintain indefinitely all mandatory permanent pupil records or an exact copy thereof for every pupil who was enrolled in a school program within said district. The mandatory permanent pupil record or a copy thereof shall be forwarded by the sending district upon request of the public or private school in which the student has enrolled or intends to enroll. Such records shall include the following:

(A) Legal name of pupil.

(B) Date of birth.

(C) Method of verification of birth date.

(D) Sex of pupil.

(E) Place of birth.

(F) Name and address of parent of minor pupil.

1. Address of minor pupil if different than the above.

2. An annual verification of the name and address of the parent and the residence of the pupil.

(G) Entering and leaving date of each school year and for any summer session or other extra session.

(H) Subjects taken during each year, half-year, summer session, or quarter.

(I) If marks or credit are given, the mark or number of credits toward graduation allows for work taken.

(J) Verification of or exemption from required immunizations.

(K) Date of high school graduation or equivalent.

(2) "Mandatory Interim Pupil Records" are those records which schools are required to compile and maintain for stipulated periods of time and are then destroyed as per California statute or regulation. Such records include:

(A) A log or record identifying those persons (except authorized school personnel) or organizations requesting or receiving information from the record. The log or record shall be accessible only to the legal parent or guardian or the eligible pupil, or a dependent adult pupil, or an adult pupil, or the custodian of records.

(B) Health information, including Child Health Developmental Disabilities Prevention Program verification or waiver.

(C) Participation in special education programs including required tests, case studies, authorizations, and actions necessary to establish eligibility for admission or discharge.

(D) Language training records.

(E) Progress slips and/or notices as required by Education Code Sections 49066 and 49067.

(F) Parental restrictions regarding access to directory information or related stipulations.

(G) Parent or adult pupil rejoinders to challenged records and to disciplinary action.

(H) Parental authorizations or prohibitions of pupil participation in specific programs.

(I) Results of standardized tests administered within the preceding three years.

(3) "Permitted Records" are those pupil records which districts may maintain for appropriate educational purposes. Such records may include:

(A) Objective counselor and/or teacher ratings.

(B) Standardized test results older than three years.

(C) Routine discipline data.

(D) Verified reports of relevant behavioral patterns.

(E) All disciplinary notices.

(F) Attendance records not covered in the Administrative Code Section 400.

11 APPENDIX E

HISPC Stakeholder Group Participation

	HISPC WORK GROUPS					OUTREACH TO STAKEHOLDERS		
Stakeholder Group	Steering Committee (X)	Variations Work Group (X)	Legal Work Group (X)	Solutions Work Group (X)	Implementation Planning Work Group (X)	Variations assessment (N)	Solutions development & evaluation (X)	Implementation planning (X)
Clinicians	x	x	x	x	x	14	x	x
Physicians and Physicians Groups	x	x		x	x	24	x	x
Federal Health Facilities	x	x		x	x	3	x	x
Emergency Medicine				x				
Hospitals / Health Systems	x	x	x	x	x	32	x	x
Community Clinics and Health Centers	x	x	x	x	x	19	x	x
Mental Health and Behavioral Health	x	x		x	x	5	x	x
Long Term Care Facilities and Nursing Homes	x	x		x	x	6	x	x
Homecare and Hospice	x	x		x	x	1	x	x
Laboratories		x		x	x	2	x	x
Pharmacies / Pharmacy Benefit Managers		x				2	x	x
Safety Net Providers	x	x		x	x	19	x	x

Professional Associations and Societies	x	x		x	x	10	x	x
Quality Improvement Organizations	x	x				1	x	x
Medical and Public Health Schools / Research	x	x		x	x	5	x	x
Public Health Agencies or Departments	x	x	x	x	x	16	x	x
Medicaid / Other State Government	x	x	x	x	x	15	x	x
County Government	x	x	x	x	x	15	x	x
Regional Health Information Organizations	x	x	x	x	x	12	x	x
Payers	x	x	x	x	x	11	x	x
Individual Consumers		x				3		
Consumer Organizations and Advocates	x	x	x	x	x	13	x	x
Employers	x	x	x	x	x	100*	x	x
Law Enforcement and Correctional Facilities		x				1		
Legal Counsel / Attorneys	x	x	x	x	x	15	x	x
Health Information Management organizations		x		x	x	6	x	x
Privacy and Security experts / Compliance officers	x	x		x	x	10	x	x
Health IT consultants	x	x		x	x	8	x	x

Electronic Health Records experts								
Technology Organizations / Vendors					x	3		x
Other: all but 10 participants were employers								